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SCIENTIFIC BASE FOR FOOD INSPECTION

HEARING

BEFORE THE

SUBCOMMITTEE ON AGRICULTURAL RESEARCH AND GENERAL LEGISLATION

OF THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY UNITED STATES SENATE

ONE HUNDRED FIRST CONGRESS

FIRST SESSION

ON

MEAT AND POULTRY INSPECTION PROCEDURES

JULY 20, 1989

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SCIENTIFIC BASE FOR FOOD INSPECTION

THURSDAY, JULY 20, 1989

U.S. SENATE, SUBCOMMITTEE ON AGRICULTURAL RESEARCH AND GENERAL LEGISLATION OF THE COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,

Washington, DC.

The subcommittee met, pursuant to notice, at 2:07 p.m., in room SR-332, Russell Senate Office Building, Hon. Thomas A. Daschle (chairman of the subcommittee) presiding.

Present or submitting a statement: Senator Daschle.

STATEMENT OF HON. THOMAS A. DASCHLE, A U.S. SENATOR FROM SOUTH DAKOTA

Senator DASCHLE. The hearing will come to order.

I want to thank everyone for their indulgence in the last 24 hours. We certainly had no intention of having to delay this hearing and move the schedule as we have, but under the circumstances there really has not been much choice in the matter, and I apologize to all of you for this change in schedule, and appreciate your willingness to cooperate with us in making sure that we are able to conduct the hearing this afternoon.

Federal meat inspection is a long-standing and generally successful aspect of U.S. public policy. In 1906 Congress enacted the Federal Meat Inspection Act, which mandated ante mortem and post mortem inspection of all cattle, hogs, sheep, and goats, and imposed sanitary standards on slaughter and processing facilities. In 1928, Federal inspection was extended to include poultry on a voluntary basis; mandatory poultry inspection was instituted in 1957.

Beginning in the 1970's, studies and assessments of the USDA's meat and poultry inspection system raised questions about the efficiency and effectiveness of Federal meat inspection procedures. More recently, exposés on television and in prominent newspapers, alleging that meat and poultry products pose health hazards, have caused at least some segments of the public to have doubts about the safety and quality of these products.

One of the basic problems associated with current meat and poultry inspection procedures is the fact that traditional inspection practices, which rely largely on organoplectic procedures, that is sight, smell and touch, cannot detect the presence of a number of pathogenic microorganisms and chemical residues in meat and poultry that most commonly cause human illness. Traditional ante mortem and post mortem inspection can identify diseased animals or carcasses with visible symptoms, but the absence of visible le-

sions or other imperfections by no means ensures that meat or poultry is free of pathogens.

Since 1966 the Centers for Disease Control (CDC) have operated a surveillance system that allows us to gauge the frequency and cause of foodborne diseases. These CDC data are imperfect in various ways, but they provide the best information available on the types of pathogens and foods that most commonly cause consumers to get sick or die.

As a part of the context for this hearing I will summarize the main conclusions to be drawn for the CDC data, which are well-known and widely accepted among public health experts. I want to thank Dr. Mitchell Cohen and Dr. Morris Potter of the CDC for making surveillance data as well as their previous congressional testimony available to me.

Of the known causes of foodborne disease since 1973, bacterial (as opposed to parasitic, viral, or chemical) pathogens accounted for the vast majority of outbreaks (roughly 70 percent) and cases (85 percent). Over the past 15 years parasitic outbreaks have steadily declined, while bacterial outbreaks have steadily increased. Chemical residues (from pesticides, pharmaceuticals, mycotoxins, food additives, et cetera) are the second leading cause of foodborne diseases.

Salmonella was the bacterial pathogen most frequently responsible for outbreaks (roughly 40 percent) of foodborne illness. The reported cases of salmonella infection average about 40,000 annually, but the actual number of cases is estimated to run as high as 4 million and are responsible for as many as 500 deaths.

All of the leading (top 10) individual vehicles known to have caused foodborne outbreaks of disease from 1973 to 1988 (which are broken out by CDC into discrete categories that identify products from beef and veal to rice balls and mashed potatoes) are meat, poultry, or fish products.

The CDC data make it clear that a modern system of inspection should include rapid and reliable diagnostic procedures for detecting microorganisms in meat and poultry, and one of my objectives in this hearing is to determine the extent to which the FSIS has, or is in the process of obtaining, this type of diagnostic capability.

Preventing health hazards that result from the presence of high concentrations of certain chemicals in meat and poultry requires the use of an adequate sampling system, so that the nature and distribution of chemical contaminants can be detected and characterized. It also requires accurate, sensitive, and inexpensive testing equipment, and trained personnel to conduct the tests. I want to know, through this hearing and other information we hope to acquire, whether FSIS has these different elements of the effective chemical residue program in place, or plans to have them in place at some point in the future.

I also want to explore inspection science and technology issues from the standpoint of Agency personnel. Do the changes that have occurred in the nature of foodborne diseases call for a change in FSIS recruitment priorities? More specifically, should FSIS place more emphasis on recruiting people with training in microbiology? Should there also be a change in the recruitment and training of

inspectors? To what extent are these kinds of changes taking place within FSIS today?

This is, by no means, an exhaustive list of the issues that will come up in this hearing, but I hope my remarks convey a sense of its purpose and direction; which is to determine the extent to which FSIS possesses the scientific and technological capability to protect the public from health hazards associated with meat and poultry. Any areas where this capacity is lacking need to be identified so that we can then begin the process of solving problems that currently exist. The meat and poultry industries and the public have a right to expect an inspection system of the highest quality that current science and technology permits.

Obviously we are doing all of this with an eye toward the 1990 farm bill. With an opportunity in the 1990 farm bill to examine our policies, with the vehicle there to ensure that inspections will be provided to the maximum degree possible and in the best way. We hope to begin our information gathering today and continue during the next several months.

So again, let me welcome all of our witnesses to the committee this afternoon.

At this time, let me call the five witnesses who will comprise the first panel. They are: Mr. Thomas Grumbly, the president of Clean Sites, Incorporated, of Alexandria, Virginia; Dr. John Bailar, professor of epidemiology and biostatistic, McGill University; Mrs. Jo Ann Smith, the Assistant Secretary of Marketing and Inspection Services, the U.S. Department of Agriculture; Dr. Lester Crawford, the Administrator of the Food Safety and Inspection Service; Dr. Michael Pullen, professor of veterinary medicine at the University of Minnesota, St. Paul, Minnesota.

Let me extend my thanks to all of our witnesses, to each of you.

Mr. Grumbly, let us begin with your testimony.

STATEMENT OF THOMAS P. GRUMBLY, PRESIDENT, CLEAN SITES, INC., ALEXANDRIA, VA

Mr. GRUMBLY. Thank you very much, Mr. Chairman.

Senator DASCHLE. Excuse me, if I might. The color-coded lights that you see are just one little vehicle that we might use to ensure that we are able to conduct the hearing in a way that will allow us ample time to ask questions and enter into a sort of dialog. Each witness will have 5 minutes to present their formal testimony. Obviously, their entire text of whatever prepared statement they may have brought to the subcommittee will be inserted in full in the record.

So with that, Mr. Grumbly, excuse me, and let us begin.

BACKGROUND

Mr. GRUMBLY. Again, thank you, Mr. Chairman.

My name is Thomas P. Grumbly. I appreciate the opportunity to testify today before this subcommittee in its examination of the Nation's meat and poultry inspection system, and to reacquaint myself with some of my former colleagues, particularly Dr. Crawford.

I am currently president of Clean Sites, Incorporated, which is a nonprofit corporation dedicated to cleaning up the Nation's abandoned hazardous waste sites. But I am here today in my capacity as a past member of the National Academy of Sciences National Research Council Committee that examined the Scientific Basis of the Nation's Meat and Poultry Inspection Program during 1984 and 1985. It is a pleasure to be associated—on my left—with Dr. John Bailar, who is also a member of that committee. The two of us have in some ways coordinated our testimony here today.

Before undertaking this review of what the Academy found, I would like to at least summarize a bit of my own background. For the last 12 years—at least prior to 1987—I was intensely involved in the meat and poultry inspection arena, first at the White House Office of Management and Budget. Then I had the distinct pleasure and opportunity to help run the program along with Assistant Secretary Foreman, the Food Safety and Inspection Service during the Carter administration. I oversaw some of the aspects of this program as staff director for the House Committee on Science, Space, and Technology, Subcommittee on Investigations and Oversight, during 1981 and 1982, and then as a member of these committees.

I do not claim to be a scientist. The Academy asked me to be their "regulatory and policy expert" in these things, and that is, of course, something that one undertakes dangerously in these areas.

Right now, I claim not to be right about all of this but to have a fairly unique perspective of being associated for a long time, and also being economically disinterested in the outcomes. I want to see this program succeed.

ACADEMY STUDY AND MAJOR CONCLUSIONS

From this rather unique vantage point, then, let me summarize a little, the context for the Academy study, and then lay out its major conclusions as I saw them.

The 1984–85 Academy study was convened, to use the report's words, but also your own, because some of the recent changes that the Department had envisioned, in fact were drawing fire from not simply the consumer community but also from some of the inspection community itself. There were concerns about the rate at which slaughtered animals moved through the inspection process, the necessity and efficiency of 100 percent ante mortem and post mortem inspection of groups of animals that seem to be nearly uniformly healthy; the actual health hazards that were presented by microbial contamination of the meat and poultry supply; and the health effects of low levels of contamination of meat and poultry by pesticides, drugs, and environmental contaminants.

As a result of those concerns—and also I would say culminating over a decade of concern about these problems—the Academy was asked by the Department, and specifically by its late and distinguished administrator, Dr. Donald Houston, to take a look at this program. Don Houston was a man, as everybody who has been involved in this area knows, was a dedicated career person at USDA, but also dedicated to trying to improve the future course of events, and he was in many ways the driving force behind the Academy's task.

I think it is important and appropriate, given the charge to this subcommittee, to underscore that the Academy's charge was to evaluate the "scientific" basis of the Nation's program, *not* to decide whether the Inspection Service was doing per se a good or a bad job. By *scientific,* I believe the Academy committee came to mean that certain fundamental questions needed to be asked, such as:

FUNDAMENTAL QUESTIONS NEEDED TO BE ASKED

First, did the meat and poultry inspection system have clearly defined objectives that lend themselves to analysis and evaluation?

Second, did the inspection system have the facts, the data, to determine which of the myriad problems it is supposed to address, pose the greatest health risk to the public?

Third, did the inspection system have the information to determine what changes, if enacted, would have the greatest impact on the public health?

Fourth, did the inspection system have the ability to access the latest biomedical and engineering technologies that affect its ability to do its job?

Fifth, did the inspection system have access to appropriate levels of research within the USDA itself and national research system that could help alleviate its problems?

Sixth, did the inspection system have an adequate number of professionals with the variety of professional and scientific training that is necessary to a modern food inspection system?

Seventh, did the inspection system have the ability to develop field experiments and evaluations that were found to be credible by the broadest scientific and engineering community of the Nation?

Finally, did the inspection system expose its findings about change to the fullest discussion within the scientific and public health communities of the Nation?

Mr. Chairman, you have, I think, the full report of the Academy committee, and I would like to be sure that this document gets submitted for the record.[1]

FINDINGS

I would just summarize, finally, the National Research Council's findings on this by saying that we found that the meat and poultry inspection program of the FSIS has in general been effective in ensuring that apparently healthy animals are slaughtered in clean and sanitary environments. There were some aspects of the inspection system that were poorly defined in terms of objectives relevant to the public health.

I think those same findings could be carried on onto new processing procedures where the Academy found that new procedures were not likely to diminish the protection of the public health. However, the committee could find no clear evidence that the traditional inspection system and modifications to it over the years

[1] The National Academy of Sciences (NAS) report, "Meat and Poultry Inspection: The Scientific Basis of the Nation's Program," is retained in the subcommittee file.

were based on objectives and criteria that related to the public health.

[The prepared statement of Mr. Grumbly appears at the conclusion of the hearing.]

Senator DASCHLE. Excuse me, we will make sure that your entire prepared statement will be made a part of the record as well as the report that you have indicated was part of your testimony. I thank you.

Dr. Bailar.

STATEMENT OF JOHN C. BAILAR III, DEPARTMENT OF EPIDEMIOLOGY AND BIOSTATISTICS, FACULTY MEMBER, McGILL UNIVERSITY

Dr. BAILAR. Thank you, Mr. Chairman. My report really is in the volume Mr. Grumbly has presented to you and in a follow-up report that focused on the inspection of poultry, and went into more detail. My written statement, that you have for the record, is short. My oral statement can be even shorter.

There are just three points that I would like to mention now. The first is to keep in mind that inspection of meat, poultry, and their products has many purposes. The protection of human health is one of the important ones in that list, but it is by no means the sole target of inspection.

The second is to give maximum support to Mr. Grumbly's statement about the need to answer fundamental questions and the need for research analysis and careful interpretation prior to making major changes, and to make sure that those changes are adequately supported and their effects are adequately understood.

The third is a personal interpretation of the work of the two committees that is best expressed by saying that long-run solutions are likely to have to be based on concepts of preventing problems rather than identifying specific animals with problems and removing them from the food supply. This may require much more extensive overhauls of our approaches and our mechanisms than has been carefully worked out to this point.

CORRECTION

Finally, I would just like to make a small correction. The witness list is entirely correct in showing my present affiliation with the U.S. Department of Health and Human Services, but I am here today as a faculty member from McGill University.

Thank you.

[The prepared statement and appendixes 1-3 of Dr. Bailar appear at the conclusion of the hearing.]

Senator DASCHLE. Thank you, Dr. Bailar. The record will be so corrected.

Dr. Pullen.

STATEMENT OF MICHAEL M. PULLEN, D.V.M., PROFESSOR/EXTENSION MEAT HYGIENIST, COLLEGE OF VETERINARY MEDICINE, UNIVERSITY OF MINNESOTA, ST. PAUL, MN

Dr. PULLEN. Yes, Mr. Chairman.

Following the testimony of two other fellow NAS committee members, I have been asked to comment on and to assess the progress of FSIS on several key NAS recommendations.

ASSESSMENT OF FSIS PROGRESS

My assessment of FSIS progress since the release of the 1985 NAS report in the specified areas are the development of rapid and expensive screening tests to detect a broad array of chemical compounds and biological products that may be hazardous to the consumer has been very slow. However, FSIS should be commended for its successes and its continued emphasis in developing tests.

An adequate sampling plan designed to protect consumers from exposures to chemicals that are not randomly distributed across the United States. A truly successful program would embody the hazard analysis critical control point approach with control directed at the farm level.

Such a hazard program would require animal identification back to the farm of origin, a certification-verified production program, and routine monitoring of animals at slaughter for compliance.

Because of the various Federal and State agencies involved, progress in this area has been painfully slow. A most recent commendable FSIS success has been the SOS implementation and subsequent dramatic reduction in percent violations for sulfamethazine in swine.

As previously mentioned in my written report, the FSIS strongly endorses a HACCP concept but has been slow in implementing it. Improvement could be made in this area, particularly in processed meat and poultry products.

A mandatory system of initial and continuing education for inspection personnel that emphasizes food science, food technology and public health. Food inspectors have been encouraged to take self-study courses and attend university classes to improve their expertise in these areas. Veterinary medical officers can attend night courses with tuition paid by FSIS. Several VMO's have been trained at Johns Hopkins University, University of Georgia, and more recently, there was a contract with Texas A&M. It is anticipated that further training will be provided.

A substantial scientific and technical FSIS staff of respected scientists play a substantial consultive role in the development of policy. FSIS has a number of outstanding individuals that meet this need. However, significant additional numbers are required due to retirements and unmet needs. In their hiring process and educational opportunities, FSIS is adding new members to its scientific base.

Utilizing advisory committees such as the Meat and Poultry Inspection Advisory Committee, Microbiology Advisory Committee and consulting groups, FSIS continues to enhance this scientific/technical expertise. It has been envisioned that combinations of the above will be required to continue to address FSIS scientific/technical requirements.

[The prepared statement of Dr. Pullen appears at the conclusion of the hearing.]

Senator DASCHLE. Thank you, Dr. Pullen.

Mrs. Smith.

STATEMENT OF JO ANN R. SMITH, ASSISTANT SECRETARY, MARKETING AND INSPECTION SERVICES, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC

Mrs. SMITH. Mr. Chairman, as the Assistant Secretary of Agriculture for Marketing and Inspection Services, I appreciate the opportunity to appear before this subcommittee today. I will present an overview of our plans, and Dr. Crawford, our FSIS Administrator, will provide more specific details.

MODERNIZATION OF FEDERAL MEAT AND POULTRY INSPECTION

Modernization of Federal meat and poultry inspection over the last 15 years has moved the program closer to the optimal inspection system suggested in the 1985 report of the National Academy of Sciences (NAS): "Meat and Poultry Inspection: The Scientific Basis of the Nation's Program. This administration is committed to progress in meat and poultry inspection, and we will continue to modernize the program in keeping with good science. We need to pursue research initiatives that will enhance inspection modernization. We also need to more clearly communicate our objectives and the scientific basis for our actions.

The industry prospered by developing new technology, and the inspection program has systematically adapted to these changes. As new science becomes available, it is incorporated, making today's program the very best that it can be. The challenge now is to adjust to changing public health risks. In earlier days, disease detection was the primary focus of inspection. Today, the primary risks are unseen hazards, which require a modern laboratory capability as well as in-plant inspectors. This is the area where research initiatives are most needed.

THE INSPECTION PROGRAM HAS COMPILED AN ENVIABLE RECORD, AIDED BY CAPABLE LEADERSHIP

The inspection program has compiled an enviable record, aided by capable leadership. Systematic planning processes have set program objectives and established guideposts for modernization initiatives, and a modern program will certainly look to the future to continually implement and make certain that these are in place. The reduction of risk from microbiological and chemical contamination is our most pressing need. We need, first, to expand our knowledge—to better understand the source, mode of transmission, and methods of controlling pathogens.

IMPROVED COMMUNICATION

We are confident in the safety and quality of our food supply and in the soundness of actions taken to date to modernize inspection, and we feel this confidence is shared in the scientific community. It is not enough, however, to use the best science and to make the right judgments if the perception in the public does not have confidence in our actions. We are, of course, to be taken to task. We need to improve the public's understanding of the rationale and scientific basis of the inspection program, and we intend to do this.

This includes educating the public about risk. Risk communication is a two-way street. Analysis of public reaction to perceived and real risks helps policymakers understand why people judge certain risks as they do, and that aids in decisionmaking. Our goal, Mr. Chairman, is full and open communication about relative hazards, providing the public the opportunity to make informed, rational decisions. This may have diverted from previous actions, but we realize the point and the necessity of communications.

Communication will also enhance our ability to improve inspection. Modernization has too often been equated with reducing the inspection force, substituting computers for inspectors, and turning over the Government's responsibilities to the industry. These misconceptions illustrate that although inspection initiatives are sound and supportable by science, the public needs to more clearly understand our objectives if it is to endorse our actions.

OUR MESSAGE

Our message is this: a modern inspection program is a better, tougher inspection program because it focuses on the true risks to the public and the true problem plants. We are committed to maintaining the current employment level in the inspection force. The strict inspection standards and the authority of the inspectors have, in no way, been diminished. We have made it clear to processing inspectors that food safety requires that they continue to use their experience and individual judgment in making inspection decisions. The primary objective of meat and poultry inspection is protection of the public health; every action we take supports that objective.

FOOD SAFETY IN USDA

Secretary Yeutter has set forth the tone for USDA by saying that he will devote more personal time to food safety than his predecessors, and certainly that is a commitment on our part. Research is very critical, Mr. Chairman, and USDA and this office is committed to a strong partnership with our employees, the public, the industry, and the Hill as we continue to pursue the initiatives that are necessary to maintain a strong food protection program.

Thank you.

[The prepared statement of Mrs. Smith appears at the conclusion of the hearing.]

Senator DASCHLE. Thank you, Mrs. Smith.

Dr. Crawford.

STATEMENT OF LESTER M. CRAWFORD, ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC

Dr. CRAWFORD. Thank you, sir.

I welcome the opportunity to discuss the scientific and technological readiness of the Food Safety and Inspection Service to implement reforms in the domestic inspection program, as well as food safety research needs for the future. We are proud of the Agency's accomplishments in modernizing inspection, thanks to the contin-

ued support of Congress and the administration for this critical mission of public health protection through food safety.

FOOD PROTECTION NETWORK

The U.S. food protection network, including Federal, State, and local health agencies, is here to prevent public health concerns from becoming public health hazards, and it has been very effective.

REPORT AND FOLLOWUP PUBLICATION

Much mention has been made already of the importance of the National Academy of Science's report on meat and poultry inspection in the followup report on poultry slaughter inspection procedures. We are also bringing to your attention, and hope that it will be part of the record, that we published our response to the National Academy of Science studies called "FSIS Future Agenda Response to the NAS Recommendations." [2]

Since that time, we have published in 1989 a followup publication, which is our long-range plan for 1989 to 1993. Both of these documents summarize the Agency response to the NAS study, and also indicate our plans for continuing to implement the broad guidelines set out by those studies.

NAS COMMITTEE RECOMMENDATIONS

That committee made recommendations in five broad areas: public health risks related to biological agents; risks related to chemical agents; production of food animals; meat and poultry processing and inspection; and advanced technology.

We took those and implemented various aspects as soon as possible, and set forth on a course in which to find six FSIS organizational objectives, and these are: public protection; risk-based allocation of resources; use of advanced science and technology; shared responsibility with industry; enhanced enforcement; and more efficient human resource utilization.

RESEARCH NEEDS

Let me turn, finally, Mr. Chairman, to the issue of research needs. I am aware that $6 million for such research is now being considered by the Congress for fiscal year 1990. Our research needs fall into two basic areas: microbiological risks and chemical risk reduction.

Through an annual agreement, the Agricultural Research Service has completed many research projects for FSIS needs over the years. Last year, other ARS funds were redirected to food safety projects.

RISK ASSESSMENT

Risk assessment is becoming increasingly important to determine priorities for research and regulation. This is the process by which

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[2] "FSIS Future Agenda Response to the NAS Recommendations," can be found on pp. 81-108 and the FSIS long-range plan 1989-93, "Inspection Horizons," is retained in the subcommittee file.

the qualitative or quantitative characterizations are made of the potential health effects of particular substances on individuals and populations. Risk assessment includes: identification of potential hazards; information on infective or toxic doses; assessment of the number of people likely to be exposed and to what amount; and the risk characterization of the economic and social impacts.

MICROBIAL RISK REDUCTION

Now, in microbial risk reduction, we need to improve our understanding of the sources and modes of transmission of foodborne and waterborne pathogens in order to develop and implement effective control measures. This is particularly true for bacterial species such as salmonella and campylobacter, but it is also true for parasites and viruses.

PATHOGENS

We also need to learn more about the resistance of pathogens to heat, freezing, pH extremes, water activity, oxygen, and other factors that influence microbial survival and thus food safety. Established truths, such as the ability of refrigeration to halt growth of all pathogens have been overturned in recent years.

NEW AREAS OF DETECTION

The need for innovative, rapid, automated, and cost effective detection methods has already been mentioned. Gene or DNA probes, monoclonal antibodies and other biosensors, and ultrasound are the newest areas of detection methodology that can be more fully utilized to produce useful methods.

Some bacteria produce toxins, and some toxins are heat-resistant. Thus, it is important to more fully understand the conditions under which bacteria produce harmful toxins, their mode of action, and ways to prevent or eliminate toxins.

We need to define parameters for both the composition and treatment of food to assure its continued safety under a variety of conditions of handling and storage. This is particularly true for new products in new packaging. We also need to learn more about the risks of fresh and marine food products, and the cost of foodborne illness.

CHEMICAL RISK REDUCTION

Finally, we need to identify and accurately quantify the long-term chronic effects of potential chemical hazards in order to define negligible risk.

We do need more analytical methods, particularly multiresidue screening methods. We need to delineate the movement through the food chain of animal drugs, food, and drug additives, pesticides, sanitizers and environmental contaminants.

This concludes my testimony, Mr. Chairman. Thank you very much.

[The prepared statement of Dr. Crawford and the attachment "Response to the National Academy of Sciences Report—Elements of an Optimal Inspection Program," Food Safety and Inspection Service, appear at the conclusion of the hearing.]

Senator DASCHLE. Thank you, Dr. Crawford, and I thank all of our witnesses.

As the new chairman of this subcommittee, I obviously have a good deal to learn, and this is an issue that interests me a great deal. I would like to begin our questioning by asking a couple of very general questions.

I would like to get a better sense from the five experts before us right now as to whether it is your view that the Department of Agriculture has the scientific information and the technological tools necessary to carry out their responsibilities in meat inspection today?

Mr. Grumbly, let's begin with you.

Mr. GRUMBLY. I think they have made a very strong start, but I think that they—we, because I include myself in this having been there—that we were starting from very far back around 1977, and that over the last decade, there has been an awful lot of improvement in the program.

Bringing in somebody like Dr. Crawford with the kind of academic experience that he had prior to reaching USDA was a very positive thing, but I think that there is still a long ways to go before the public health research community and the biomedical research community would say that USDA was at the state of the art in a lot of these things.

Senator DASCHLE. Would you agree with that, Mrs. Smith?

Mrs. SMITH. I do not know that we will ever be at the state of the art.

Senator DASCHLE. Really.

Mrs. SMITH. No, I would think that it is——

Senator DASCHLE. Why do you say that?

Mrs. SMITH. I think science is changing that rapidly. I would hope that we would always be able to look to the future and move to the future because what was originally established, and the reason that the Inspection Service was established originally has moved so much more in the scientific arena today than it was when it was first established, and I take what Mr. Grumbly says, but I think we most of all have to be able to look out and try to be able to perceive what is going to be coming down the road and what the needs are.

But just with the technology—and I am a layman—but just with the technology changing as rapidly as it is, I think that we certainly should look toward always being open to change and moving forward.

Senator DASCHLE. I think Mr. Grumbly would certainly not argue that. I think he is saying we are not at the state of the art. The state of the art, as I understand the term, means you take the current applicable scientific or technological data and you apply it to whatever it is you are doing to the maximum degree possible. I always expect that state of the art to continue to change.

Mrs. SMITH. That is correct.

Senator DASCHLE. But you say you would agree that we are not at the state of the art today.

Mrs. SMITH. I would say that the state of the art is changing that rapidly. I repeat just exactly what I was saying. I think it is changing daily.

Senator DASCHLE. Dr. Bailar.

Dr. BAILAR. I agree to a large extent. I have been very favorably impressed by the staff of FSIS at all levels. We talked with people from the top right down to the grassroots, and overall they are capable, knowledgeable and dedicated to doing a good job. I really appreciate a chance to put that on the record.

At the same time, they do not have all of the tools they need because those tools do not yet exist, hence the need for research. I think Mrs. Smith is correct in pointing to an inevitable lag between research and application, but I think that lag can be shortened. It is not going to be easy, but I have no doubt also that FSIS is dedicated to keeping that lag as short as possible. You cannot get it down to zero.

Senator DASCHLE. Dr. Pullen, do you have anything to add to that? Do you disagree?

Dr. PULLEN. No, I agree with Dr. Bailar. I think FSIS is certainly making a lot of effort. There are a lot of new techniques that are being developed and are being implemented. They are taking advantage of it to every extent possible.

I would like to emphasize, though, that FSIS is a regulatory agency. Any quick-fix tests will not necessarily hold up under legal circumstances. So they have to verify their results if they want to take legal action. That creates a little different situation.

Senator DASCHLE. Dr. Crawford, has anything been said that you disagree with?

Dr. CRAWFORD. No, there is one aspect of it that we are trying to utilize, Mr. Chairman, in order to get a better fix on all the available technology.

For years—as you know and other panelists know—our country has been in the lead in food safety protection and in research. We are finding, though, that countries that we deal with internationally are also making great strides, and we cannot afford to ignore developments in other nations and in institutes around the world.

We have just reactivated a committee on meat hygiene under one of the arms of the United Nations which is going to meet next year in order to share information between the majority of the 140 nations that belong to this organization. We hold out great stock in that, this sharing of information back and forth, and also utilizing developments in other countries to bring them as fast as we can here.

We do not have to reinvent the wheel. The chemical residue test that is useful in South America is also useful here, so we are working very hard, and we think this committee on meat hygiene is going to help us a great deal.

Senator DASCHLE. Help me with my confusion. I have toured a lot of facilities in South Dakota and Iowa, and the only thing I see is this organoleptic approach to meat inspection. That is all I see.

You are telling me that FSIS is using state of the art or close to state of the art, that they are adapting to new methods as science and technology moves us along. Why don't I see that when I tour my meat packing facilities? What am I missing, Mr. Grumbly?

Mr. GRUMBLY. When I said that we were starting from a long ways back, I really meant that in the sense that the problems that you point out, the problems of salmonellosis, the problems of micro-

bial contamination were problems that in my view USDA did not attack back in the 1960's and the 1970's as vigorously as we should have, that they did not bring in the kind of research that was available even at that time, that we were not putting the kind of money into it at that time and the kind of effort to come up to speed.

As a result, when we go out today to look at some of these places we see known problems, problems that all of us around the table would agree to still being addressed in ways that none of us would think is optimal. So I think we are still behind the curve in terms of what the technology actually is.

Senator DASCHLE. That is a very euphemistic way to look at the current situation, it seems to me.

What I see is that nothing has changed in my lifetime. Where is the evidence that the assertion that I am hearing from all of you that we are really making strides in that while we will never be at state of the art, by golly we are really inserting as much scientific and technological data as we can to find new methods of meat inspection? Where is the evidence of that, Dr. Pullen?

Dr. PULLEN. If I could make a comment. If you go into a hog slaughtering establishment, you will see them using the Sulfa-on-Site test (thin layer chromatography) for looking at urine samples for sulfamethazine violation. It has been an extremely successful program. They have gone from 4 to 6 percent violative levels down to less than six-tenths of a percent.

Senator DASCHLE. That is in hogs?

Dr. PULLEN. Hogs.

Senator DASCHLE. Why do we stop with hogs?

Dr. PULLEN. Well, I would envision that that test will be developed for other species as well, but you mentioned that there had not been any changes, but there are some things occurring, and there is lab support that occurs outside the plant where samples are submitted for analysis that are not necessarily done in the plant.

Senator DASCHLE. Well, it leads me to the question that obviously comes as a result of discussion like this. Can FSIS on its own, without additional authority either from Congress or from the Department, can it implement these changes unilaterally? Can it take it upon itself to make these changes in technological and scientific advancement by themselves? Who can answer that?

Dr. CRAWFORD. I will attempt to address that. I think we do one activity that is captured in a part of my testimony that I did not mention, and that is we have each year a priority setting exercise with the Agricultural Research Service, which is an open meeting. This year it is taking place in December, and we characterize what are the most needed research projects for our Agency each year. We also get public input and academic input and so forth, and each year we are able to fund through USDA research about half of that which we need.

Now, to say that we need twice as much money as we are now spending on food safety research, I think probably would be about in the ball game, but we cannot utilize it—that is, we have to spend it wisely, and we have to have the capacity for doing the research, and then putting it into effect.

We are getting there. We are getting there slowly. We could use some more funds, obviously, but I think the defining of the needs has been very successful since we started this in 1981. It is just a question of maybe not getting to all the needs each year that we have.

Senator DASCHLE. I still do not know the answer to my question. How capable is FSIS in adapting to what Mrs. Smith addressed as the state of the art in inspection processes today?

Dr. CRAWFORD. Well, again, I think whenever a technique is available like this [rapid Sulfa-on-Site] SOS test that we had to develop ourselves, I believe the record will show, Mr. Chairman, that we have been effective in putting it in place.

The major technological developments in the 1980's for improving meat inspection have practically all been developed on a worldwide basis somewhere in USDA or at least somewhere in the United States, and we have put them in place I think rapidly and effectively.

Senator DASCHLE. So you would all agree, judging from the response that I have been given, that they can adapt very rapidly, and that you are fairly satisfied with the ability FSIS has demonstrated in meeting new opportunities with whatever new information is presented them?

Mr. GRUMBLY. Well, I do not.

Senator DASCHLE. You do not?

Mr. GRUMBLY. I do not. I mean that is where I started from.

Until 10 years ago, this Agency did not view itself as a science-based agency. It did not view the problems as ones that were fundamentally based in science. They did not have anybody like Les Crawford running the show at that point. In the last 10 years, it has tried very hard to try to accommodate itself with the Agricultural Research Service and the other research agencies of the Department of Agriculture. It gets part of the way there, and this crosses the political spectrum. It did not matter whether it was Democratic or Republican administrations.

What this organization needs, one way or the other, Mr. Chairman, whether through the appropriations process or through the authorization process, it needs to have a serious scientific and research component that is responsive to the needs that it has because if you do not have that, the lag time between the identification of the problem and the ability to generate solutions will be longer than the American people need to tolerate.

The problem that this system has had is that as they have gone forward to make changes, the system has not been able to back it up with the kind of data and information and techniques that give my mother or your mother confidence that they know what they are doing out there.

I would say that until that kind of public confidence grows so that the scientific community creates that—for the lack of a better term—"warm fuzzy" feeling about what agriculture is doing out in the world where we are going to continue to have problems.

As you know, they have constraints about saying what the Office of Management and Budget wants them to say or anything else. And I will just tell you straight out, unless they get more research

authority or more research dollars, they will not do the job that you want them to do, because they cannot.

Senator DASCHLE. Let me just ask, if 50 years ago the entire meat inspection process was, as they term it organoleptic, today it is obviously not 100 percent. Dr. Pullen mentioned some of the chemical testing that now goes on. What percent is organoleptic and what percent is based upon the need to look for pathogenic microorganisms and other chemical residues?

Mr. GRUMBLY. It depends on what your objective is. And I do not mean to be monopolizing the conversation. If your objective is public health, then a very small percentage of the current inspection program—although I am sure it is growing—and the resources have really been devoted over time to the public health problems, if our assumptions that the mean public health problems presented to the meat and poultry inspection system are the problems of microbial contamination and chemical contamination.

If, however, you will go further and you ask yourself, what do we want to eat as a society, and you include a broader definition of wholesomeness, then under that definition, a lot of the organoleptic inspection that the Agency does is probably justified and important. I mean, I do not particularly want to go to the supermarket and buy food that has bruises on it.

But I would say to you that Frank Perdue has probably a greater incentive to produce organoleptically attractive chickens than the Department of Agriculture does. And so with limited resources, trying to balance how we go, it seems to me that is a major issue that is involved here.

And when Assistant Secretary Smith says, look, our primary objective is the protection of the public health, I think she has it right absolutely. But what needs to be done is to say how do we move our resources over time to get them in line with those objectives and still persuade the American people that we are doing the right thing, that we are not backing off?

Senator DASCHLE. Well, let me ask you this. In your view, what is the threat to public health from microbiological and chemical contaminants today? Is it a problem?

Dr. CRAWFORD. Yes, it certainly is a problem.

Dr. PULLEN. I was on a committee of 18 societies to draft research priorities. Certainly by far the most serious public health hazards would be microbiological organisms.

Senator DASCHLE. Serious public health hazards?

Dr. PULLEN. Yes, from the standpoint of illness. You have received the data from CDC. People are becoming ill.

Probably less important is chemicals, although it is perceived to be very important by the population, so therefore it cannot be dismissed. But I would certainly say that microbiological hazards are certainly out there and they do represent a significant cost.

Dr. CRAWFORD. Might I just mention a couple of them that have come up? And this goes back to Mrs. Smith's comment about the ever-changing state of science and also of hazards.

Two significant threats have developed since the Academy published its reports. One is the threat of *Listeria* contamination of meat, which was first appreciated in late 1985. The Agency, that is FSIS, did not have at its disposal a test to even detect it rapidly

enough to do any good. We had to go back to ground zero and devise a test for discovering it in meat, and also put in place a program of regulation that would prevent products contaminated with *Listeria* from entering the marketplace.

The second one occurred even later. I have only been at USDA 3 years, and both these developed in that time. The second one was an organism called hemorrhagic E. coli, which was not appreciated by anyone until about 2 years ago as being a serious threat through meat. And again, we had to develop tests and also to put in place a regulatory program to deal with that.

We have a third one which is mentioned in the testimony which was not fully appreciated either, and that is *Yersinia enterocolitica.* We are working now to try to do the same two things, develop a rapid test and an effective test, and also put in place a regulatory program.

Senator DASCHLE. I had some specific questions I wanted to ask of each of you. Since Dr. Crawford just answered that question, let me ask you, with regard to the hazard analysis critical control point system, how much progress has FSIS made in identifying critical control points for microbiological and chemical hazards so that the public can be sure that pathogens carried by meat and poultry can be prevented from entering the food supply? Also, what are the principal problems you have encountered in moving ahead with HACCP?

Dr. CRAWFORD. Well, we have had a number of quality control programs that we started a number of years ago, about 8 years ago, beginning to implement HACCP principles. And as you know, HACCP principles developed as a result of the space program in the sixties and early seventies. And they will work for almost all food production.

We have gradually come to the point of introducing HACCP. I must say it has been slow. We continue to have new task forces put in place to apply it to meat and poultry inspection. It has not been an easy leap for us, Mr. Chairman, but we are still working to implement it.

Dr. Pullen mentioned earlier that he is not particularly satisfied with the progress. And I think none of us are. We believe in Hazard Analysis Critical Control Point (HACCP). We are attempting in every way that we can to modify it to our programs. We have recently put on retainer the person who developed HACCP, Dr. Howard Bauman, adding him as a consultant to our efforts in order to implement these principles. We believe that is going to help.

We also are using, finally and quickly, the National Advisory Committee on Microbiological Criteria in Food, which we constituted with the Food and Drug Administration a year and a half ago. And, we are asking them regularly what we should be doing, how we should be doing it. And their main thrust in meat and poultry, as well as in seafood, is to infuse HACCP into every and all levels of regulation.

So because of that committee, I must say we have a renewed effort. But we have been slow.

Senator DASCHLE. Yes, Mr. Grumbly.

Mr. GRUMBLY. Mr. Chairman, Dr. Crawford brings up the issue of seafood here. And I know that you all are considering that. And if the regular food supply, 85 percent of the food supply that is not meat and poultry, the 10 percent that is meat and poultry, have some problems, the fish industry has big problems because they have essentially been unregulated for a long time. If we are talking about bringing them under the same kind of inspection that we are talking about here, that just reinforces the need to make the kind of investments in the science of this whole business, the microbial contamination problem in particular, so that we get on top of that. Because once we start being serious about fish inspection—which I do not think that we have ever been as a society—these issues are going to multiply in that arena as well. So, that is, I think, something that is important to keep in mind as you shape legislation in that area.

Senator DASCHLE. Let me ask Dr. Crawford, or anybody else who cares to respond, about FSIS's ability to detect the presence and level of salmonella or any other microbial contaminants in meat and poultry in a manner that allows them to prevent dangerously contaminated products from entering the food supply. How confident are you at this point, Dr. Crawford, that we can do that?

Dr. CRAWFORD. We are quite confident, Mr. Chairman. We have been steadily improving our tests over the years. For ready-to-eat products, that is those products that do not require further cooking, we are confident that we are doing an effective job and that we have tests that work. We will always need quicker tests, and we will always need tests that are evermore accurate for legal reasons.

Now, for raw products, that is those products that require further cooking or that have not been cooked or processed at all, we do not enforce, as you know, that they be sterile because we know that they require further cooking. We do monitor for salmonella and other organisms. And you know, we report those results regularly, but we do not interdict those from the food supply.

Senator DASCHLE. Are you in disagreement at all with the CDC's analysis of salmonella and the number of reported cases?

Dr. CRAWFORD. That they have 40,000 reported cases a year?

Senator DASCHLE. That is right.

Dr. CRAWFORD. No, I am not.

Senator DASCHLE. OK. Just for my own background, can you detect salmonella fairly easily through the organoleptic process of inspection?

Dr. CRAWFORD. You do not detect it at all through the organoleptic process. You have to take a sample of the food, then analyze it in the laboratory.

Senator DASCHLE. You have to take a sample of the food. Does that happen as part of the regular inspection process?

Dr. CRAWFORD. It happens on a random basis. We do not sample every lot, but we sample on a random basis.

Senator DASCHLE. Well, how is it that your confidence runs as high as it does then with regard to detection given the fact that we randomly inspect these carcasses for salmonella?

Dr. CRAWFORD. What we do is when we detect salmonella in ready-to-eat products, we verify its presence and order a recall of the product if product is in commerce. If it is still in the plant, we

order it retained. We have very few incidences where that does occur.

Now, with raw products, we do not have the authority, nor do we enforce, nor the public expect that they be sterile. So that is a different issue. But ready-to-eat ones, we order a recall.

Senator DASCHLE. Have you already determined the tolerance level for salmonella and other microorganisms?

Dr. CRAWFORD. With respect to ready-to-eat products, any contamination that we would detect we would order a recall. So we in effect enforce zero tolerance.

For raw products, the infectious dose varies. And there is little general agreement with most organisms. And with the advent of such a large percentage of our population being immunocompromised, that figure is really quite fluid at the present time for almost all the organisms that we have regulatory concern about.

Senator DASCHLE. Does anyone disagree with Dr. Crawford?

Dr. BAILAR. I would like to expand a little on the constraints. We are talking about a food supply system that produces many, many millions of red meat animals per year and billions of poultry. There is no conceivable way by which each one can be tested with anything other than organoleptic inspection. You cannot do the chemical or microbial tests on every animal and bird.

That means that a first requirement is that whatever is done has to control those two classes of hazards—which I think we agree are the main health hazards—has to be done on a sample basis. And the sample then must be drawn, in my view, so as to identify the broader problems; not just so that the particular animal that is tested could be removed from a food supply; but to find the bigger problems and go back and, as I said before, find the source of those problems and prevent them so that animals that carry human health hazards never get to slaughter and processing in the first place. That is one constraint.

A second is the need for a very high order of speed, because poultry particularly, but also the red meat animals, move through the plant and out into commerce very quickly. You cannot wait several days for a microbial test on an ordinary laboratory plate to be incubated and then read. You cannot wait even a few hours for chemical tests to be completed. Highly accurate microbial and chemical tests do exist, but they are not appropriate for routine use in the plants.

A third is that even on a sample basis the tests must be very inexpensive, and they must be such that persons without extensive, advanced training can implement them. And that again puts some heavy constraints on inspection.

And finally, of course, they must be very accurate, because a lot rides on the outcome, economically first, but also in those cases where various kinds of very serious problems are detected, because the legal remedies require that the tests be extremely accurate.

Senator DASCHLE. Dr. Crawford, the NAS panel recommended the sampling system for chemical residues be improved because the 95 percent confidence level for detecting chemicals present in 1 percent of animals going through the system was insufficient, in their view, to prevent public health hazards.

I understand the parameters of the FSIS sampling have not changed. Why have you not revamped the sampling system for detecting chemical residues along the lines suggested by the NAS panel?

Dr. CRAWFORD. What we did is we reviewed the NAS recommendation. We had a panel of experts that recommended that we do the following thing, that is that we institute a risk analysis of the chemical hazards likely to be present in the food supply, and we rank them in terms of how likely they were to be present and what the toxicological potency was. And because this is such an expensive undertaking, we begin with the top four or five most dangerous chemicals and then we increase our confidence from 95 percent to 99 percent with those.

We have gradually begun to do that. The expenditure of funds is enormous in order to be able to do that. And also our laboratory capacity is strained. However, we do intend on a gradual basis, Mr. Chairman, to annually—we will annually rate the chemical hazards that are in the food supply and we will gradually increase the level of testing to the 99 percent confidence level.

Senator DASCHLE. Dr. Bailar, do the other panel members feel that that is sufficient in response to the concern by the NAS?

Dr. BAILAR. I do not. I think increasing the confidence level to 99 percent is a useful step. But I am much more concerned about the other side of this. Is the level of confidence of detecting 1 problem carcass in 100 good enough? I think it is not. I think that we should go to a much more stringent level on that side rather than the probability level of finding the difficulty.

The reason is that I suspect that microbial hazards to a large extent, and chemical hazards to a far greater extent, are highly localized. It may be that there is one plant, it may be one flock of chickens, it may be one small geographic area, that does not fall in that sample of 1 in 100. If we are talking about a problem that affects only 1 in 1,000 or 1 in 10,000 animals, but very seriously, then knowing that you have a good chance of detecting the problem at a level of 1 in 100 is not enough.

Senator DASCHLE. Mrs. Smith, I know you have to leave momentarily. Let me just ask you one question.

There has been some criticism that FSIS has not been open to the scientific community for recommendations for improvement, for things that you can do. You certainly sounded as if you were well-intended in terms of staying abreast of current technology and had every interest in putting this as a high priority.

How do you respond to that criticism that FSIS is not open, that it does not involve the scientific community like it ought to? Do you think there is any legitimacy to the criticism?

Mrs. SMITH. Let me just address it with a very positive statement. We recognize that we are a new administration, and food safety is a priority. The manner in which we will address these issues, many of which have been laid out today—and I appreciate hearing this from the other persons on the panel—will be very open to anything that can help in order to protect the food supply for the public today.

We recognize that we have a responsibility. We are going to accept that responsibility very seriously. And certainly the scientif-

ic community, their technical expertise will be very open to all of us.

Senator DASCHLE. Very good.

Mrs. SMITH. Thank you.

Senator DASCHLE. Well, I know you have another appointment. So I appreciate your coming.

Mrs. SMITH. Thank you for understanding.

Senator DASCHLE. I do want to follow up, if I can, with the other witnesses just a little bit more.

Mr. Grumbly, you talked about the lack of defined inspection objectives. And I wanted to get into that a little bit. I sense that, from the little experience I have had thus far, we are all over the map with regard to what we are trying to do. I am hearing that again in my answers to the questions that I posed this afternoon.

Can somebody delineate for me what the best understanding of the objectives are and what you think they ought to be? Mr. Grumbly, since you made the case, let us begin with you.

Mr. GRUMBLY. Fine. I think that any food inspection system should essentially have two basic objectives. First, to guarantee that the food supply has the confidence of the American people. I know that sounds very general. But I think that once you go beyond that, you say well, what does that confidence consist of?

First, that it is not going to hurt you. So the public health objectives have to be paramount in the equation.

Second, that you are buying what you think you are paying for, that the products have not been economically adulterated, in other words, that I have not willy-nilly added water to my hams, that I have not done something that ends up my paying $1 for an $.80 product that is out there.

And third, that the manner in which the food was prepared was prepared in a way that is consistent with our expectations as a society about what our food should be like.

And the biggest example of that is going all the way back to 1906 to the genesis of this program, to the abuses exposed in "The Jungle." Much of the food that was reaching the public was not food that was going to hurt you in any demonstrable way. But we were repulsed as a society that some of these practices that we heard about were going on.

Senator DASCHLE. So you think those are the three objectives.

Mr. GRUMBLY. I think those are the three objectives.

Senator DASCHLE. Does everyone agree with those three objectives? Would you take any one away or add any?

Dr. Crawford, you are the most directly affected. Would you say "I agree"?

Dr. CRAWFORD. I agree, yes. I have no disagreement with that.

Senator DASCHLE. To what extent then do you think we are meeting those three objectives today?

Dr. CRAWFORD. Well, I believe we are meeting them, Mr. Chairman. As I mentioned earlier, things change in terms of hazards, so we have to be flexible. We cannot just cast an inflexible position. And we have to be particularly concerned about these microbiological hazards that seem to evolve all the time. But I believe that the Agency is structured to, on a flexible basis, meet these requirements.

Senator DASCHLE. Then if you are so confident, why do you not want what you are doing debated in the scientific community?

Dr. CRAWFORD. I do.

Senator DASCHLE. Well, there seems to be a disinclination on the part of FSIS to debate many of these questions.

Dr. CRAWFORD. Well, I cannot go back very far historically, Mr. Chairman. But for the 3 years I have been there, I have certainly suffered from no lack of debate. And I enjoy that. I mean, I think all of us do.

There could have been a time in the Agency's history where they were unwilling——

Senator DASCHLE. So you deny that you are disinclined to have any of your programs or regulations debated within the scientific community today?

Dr. CRAWFORD. I do.

Senator DASCHLE. Do all the panel members that are looking at Dr. Crawford right now share the same confidence about his enthusiasm and his excitement about the fact that his regulations and programs are ultimately going to be discussed?

Dr. BAILAR. I do. I cannot talk about the program as it existed years in the past, but I am convinced that the present staff, from top management on down, is really committed to doing the best they can on a scientific basis. And I would like to just enter a reminder that it was FSIS that requested these two reports from the National Academy.

Senator DASCHLE. Dr. Pullen.

Dr. PULLEN. I would even go further. You can go back to the Booz, Allen, Hamilton study back in about the midseventies. So as far as I am concerned it took some courage to ask the National Academy of Sciences to review the program, to address the issues, and lay out a formulation for implementing them.

Senator DASCHLE. Again, I am the least experienced of those at the table, so you will have to forgive me. But the sense I have is that from a chemical and from a microbiological point of view, we really have a ways to go, that that is our biggest concern today, both technologically as well as with the personnel involved in the process, that we are hiring veterinarians and maybe we ought to be hiring scientists, that we are still using this organoleptic process and we ought to be using more chemical and biological detection processes than we are today.

And I hear this chorus of optimism and really harmony that I frankly was not expecting to the degree that I am hearing it this afternoon. But am I wrong? Mr. Grumbly did not even mention that necessarily as an objective, but I suppose it would fit as one of the objectives you cited.

But if that is our objective, I guess I feel we have a lot farther to go than what I am hearing from the witnesses this afternoon.

Mr. GRUMBLY. Well, I think, first of all, let us give the vets their due. A lot of them are scientists already. But I think that over time this program grew out of a veterinary science background. And if we went through the professional staff of the Agency, we would find that that is still the background of the vast majority of the folks who are there.

It is absolutely clear—and I do not think anybody in the Agency debates this at the moment—that there is a much greater need than there used to be for a broader variety of people, scientifically trained people, people from the biomedical science community, people from the toxicological community, to come in and work in these programs.

Now, having said that and attracting people to these programs after this program has for the last 80 years now been focused in the veterinary science community, that is a very difficult thing. So there is a difference between hope and reality in this arena.

I have no doubt that Assistant Secretary Smith and Les Crawford, and everybody else in the Agency, wants to expand their circle. But, one, it is not so easy to attract folks once you have been inside. And, two, if you do not have the contacts, if you are not out there, if you are not going to the biological science meetings, if you are not really out on the forefront of the other areas, it is not so easy to get your ideas out there.

You cannot say you have had a peer review of a particular program that is related to salmonella or microbiological criteria and not have involved some of the key people from the National Institutes of Health. And we do not do as well at that as we should.

Senator DASCHLE. Dr. Pullen.

Dr. PULLEN. I would like to make a comment. It was during the writing of the 1985 National Academy of Sciences report it was envisioned that as FSIS moved away from the organoleptic inspection, i.e., left the quality of the product up to the plant, that in turn they would take the resources that they saved in personnel and would put that back into the chemical as well as microbiological hazards aspect.

So, National Academy of Sciences certainly recognized that there would be a redirection of emphasis, the quality being more the responsibility of the company under the monitoring of FSIS. The chemical and microbiological qualities being that of FSIS with redirected resources.

Senator DASCHLE. Last question. There is a vote on the floor, and I am going to have to get over there in just a minute. If there was a change in current law or public policy with regard to this discussion today, and you could make two recommendations with some specificity about change in current policy, whether in law or in regulation, what would it be?

Dr. Crawford, let us start with you.

Dr. CRAWFORD. Well, in terms of recommending a change in the law, we do not really have a position that we are ready to announce on that. I would just say one thing though, that——

Senator DASCHLE. I said regulation too. What would you change either in regulation or in law?

Dr. CRAWFORD. Well, we would order things so that we would be more concerned with chemical residues and microbiological hazards. As you know, Mr. Chairman, the requirement now is that we have to continue with organoleptic examination of each and every carcass, and so the vast amount of the expenditure of our budget is in doing just that.

Senator DASCHLE. So your answer is that you would change away from organoleptic to more emphasis on microbiological and chemical inspection?

Dr. CRAWFORD. Yes.

Senator DASCHLE. In regulation.

Mr. Grumbly, very briefly.

Mr. GRUMBLY. I would give them the authority to do research themselves. That would be the single major legislative change that I would make. And on the regulatory side, I would force the Agency to, even though it is tough, to establish some kind of microbiological criteria for raw salmonella products.

Senator DASCHLE. Dr. Bailar.

Dr. BAILAR. I would first give FSIS additional authority to go back to the farms and ranches to pursue the individual problems and give them the authority to do whatever is needed to correct the problems at that level so that problem animals never get into the food system.

Second, I would give them the authority to redirect resources away from the post mortem organoleptic inspection of each bird and animal and into the things that are going to have a bigger impact on public health.

Senator DASCHLE. Dr. Pullen.

Dr. PULLEN. I would like to make a comment. If you are really looking at chemicals—and let us disregard microbiological hazards—in chemicals there are clearly three ways you are going to have to go. You are going to have to be able to identify the animal back to the farm of origin. You are going to have to be able to do inplant and onfarm testing to screen the animals before they come in. And you are going to have to take severe regulatory action.

It is very well demonstrated with the Sulfa-on-Site test. You went from 4 to 6 percent down to six-tenths of a percent specifically using those three types of recommendations. Now, the point that you could put those into laws and regulations will determine the success of your program.

Senator DASCHLE. Very good.

I am going to have to vote. I am going to excuse this panel and thank them each for their excellent presentations and their information this afternoon. We will call the second panel immediately upon my return.

[Recess.]

Senator DASCHLE. The hearing will come to order.

Again, I feel the need to apologize to our witnesses and those who are attending the hearing. We had two votes rather than one. And as a result, I decided that it was probably wise for me to stay there and cast my second vote prior to the time I returned. So this has been an elongated process, and I am very grateful to all of those who have participated today for their patience and understanding.

The second panel is comprised of Mr. David Carney, the president of the North Central Council of Food Inspection Locals, American Federation of Government Employees, and Dr. James Marsden, the vice president, Scientific and Technical Affairs of the American Meat Institute.

Let me call on those two gentleman to come forward and we will take their testimony at this time. Let us begin with Mr. Carney.

STATEMENT OF DAVID CARNEY, VICE CHAIRMAN, FOOD INSPECTORS UNION, AMERICAN FEDERATION OF GOVERNMENT EMPLOYEES, AFL-CIO, WASHINGTON, DC

Mr. CARNEY. Thank you, Mr. Chairman and members of the subcommittee for inviting me.

My name is David Carney. I am a food inspector with FSIS. I also serve as vice chair of the Food Inspectors Union, American Federation of Government Employees.

TWO OBSERVATIONS

I would like to start out with two observations. One, some observers have contended that scientific advances are the way to eliminate the human element, like inspectors, from food safety responsibility. As a result, they have assumed that inspectors and their union are defensive about scientific involvements, or see it as a job threat.

The second thing is we are seeing minimal effects of the scientific community at the inspection level. Those statements are the opening lines for a food safety fairy tale. Inspectors want stronger science at USDA, because we need it to do our jobs better.

ONSITE INSPECTORS AND ADVANCED SCIENTIFIC TECHNOLOGIES SERVE DIFFERENT, NOT COMPETING FUNCTIONS

Most significant, anyone grounded in reality knows that onsite inspectors and advanced scientific technologies serve different, not competing functions. The public needs both. For example, scientific breakthroughs, such as rapid laboratory tests, can never be a *substitute* for common sense sanitation. The tests only tell us the effects of a sanitation breakdown. Inspectors are there to enforce the law and prevent the public health threats, threats that only tests can detect. To analogize, we have traffic police to enforce laws preventing accidents, not to confirm they have occurred. Similarly, any sound business leader will confirm that quality control inspectors are not enough, even if they catch all of the defects for which they check. Quality must be built into the process. So must sanitation.

Similarly, there are no rapid tests in sight to check for all the various contagious infections and diseases whose symptoms Federal inspectors regularly detect, such as *Listeria* and tuberculosis. Since we often take action against obvious cases over vehement company objections, it is clear that inspectors will be needed for a long time. We have no reason to feel threatened by science.

USDA'S COMMITMENT TO SCIENCE IN NAME BUT NOT DEED

Unfortunately, even if we were defensive, there is not enough serious science at USDA to be threatening. USDA uses the language of the scientific method but skips the substance. Qualified scientific professionals charge that the Agency has not done systematic advance studies to determine the effects of new inspection systems before they are introduced. There has not yet been a thorough

USDA study of the effect that line speeds have on contamination, although USDA has paved the way as line speeds doubled and tripled in some instances. There are not studies of the impact that new technologies—like eviscerating machines and feather pickers—have on contamination before USDA approves their use. New food technologies effectively get a blank check from FSIS. In other words, USDA is engaged in scientific blind man's bluff before switching food safety systems.

CENSORSHIP

Scientific research is censored if it could threaten public confidence in the safety of meat and poultry; and that USDA peer review is an insult to normal professional standards: the Agency buys the viewer's opinion and then gags them in case they deviate from the party line. The Agency uses invalidated methods to test for salmonella and other contamination and that the testing methods are rigged to assure that the results will not harm the public.

THE SAME PROBLEMS APPLY TO STATISTICAL SAMPLING PROGRAMS THAT FSIS USES TO SWITCH FOR CHECKING EVERY CARCASS

The same problems apply to statistical sampling programs that FSIS uses to switch for checking every carcass. They use the language of the statistics but butcher the profession's standards. The samples are so small that they do not even cover the various different sources of poultry or cattle, which means the dirty flocks or lots may be missed entirely. The sampling reviews have built-in handicaps that make it nearly impossible to flunk. Even then the USDA sample would not trigger corrective action, unless the company flunks itself in a second opinion after choosing its own sample. In my experience and that of all inspectors I know, that has never happened.

From the perspective of inspectors and veterinarians in the field, the critics are right on target. Every day we have to cope with the results of USDA's program of nonscience. Five examples should illustrate my point.

Since 1986 USDA has said it is switching to food technologists as a more scientific substitute for inspectors at processing plants.

Senator DASCHLE. Mr. Carney, I will have to ask you to summarize your statement if you will.

Mr. CARNEY. OK.

EXAMPLES

In summary, No. 1, is that we feel that the technologists are functioning as USDA has designed.

Second, the inspectors in the field feel that the changing systems lead to filth.

Three, sometimes these studies lead to misnomers.

Four, field supervisors regularly concur that some of these changes in slaughter activities are overlooked.

Fifth, the bottom line is we do not have a science program. Management goes on to contend that they have spent a lot of money out of the budget for scientific functions. We have yet to see these scientific functions funneled down into the field.

RECOMMENDATIONS IN THE PREPARED STATEMENT

And basically, I would like to conclude with some recommendations that I have written into my statement. I will not read these at this time. And we would like to, as part of an ongoing willingness to help, I request that the subcommittee submit certain questions to FSIS that other inspectors have asked me to pass along for Agency response. And I will be glad to supply this to the subcommittee at a later time.

Thank you.

[The prepared statement of Mr. Carney appears at the conclusion of the hearing.]

Senator DASCHLE. Thank you, Mr. Carney.

Dr. Marsden.

STATEMENT OF JAMES L. MARSDEN, Ph.D., VICE PRESIDENT, SCIENTIFIC AND TECHNICAL AFFAIRS, AMERICAN MEAT INSTITUTE, ARLINGTON, VA

Dr. MARSDEN. Thank you, Mr. Chairman. I am representing the American Meat Institute (AMI) this afternoon. And we appreciate the opportunity to testify.

SPECIAL TASK FORCE TO REVIEW THE MAJOR CONCLUSIONS AND RECOMMENDATIONS OF THE NAS STUDY

Following the release of the NAS report in 1985, AMI formed a special task force to review the major conclusions and recommendations of the NAS study. The full report of the AMI Special Task Force is included with my testimony. I will not go into that here.

MODERN SCIENCE AND TECHNOLOGY BE USED AS A BASIS TO ALLOCATE INSPECTION RESOURCES COMMENSURATE WITH THE PUBLIC HEALTH RISKS

Generally, however, AMI's task force agreed with the NAS recommendations that modern science and technology be used as a basis to allocate inspection resources commensurate with the public health risks. Furthermore, the AMI task force expressed its firm belief in the ability of the industry and USDA to modernize the inspection system in a way that would prove maximum efficiency and consumer protection.

CHARACTERISTICS OF AN OPTIMAL MEAT AND POULTRY INSPECTION PROGRAM

The NAS report outlines several characteristics of an optimal meat and poultry inspection program. Some of the more salient points included:

First, a maximum use of plant personnel in process-by-process and day-to-day monitoring of critical control points with FSIS oversight to ensure compliance.

Second, an inspection system with different levels of intensity, reflecting the degree of public health risk at various stages in the process, the reliability of the monitoring system, the compliance history of the slaughterhouse or processing plant, and the special needs of the intended consumer.

Third, emphasis on Hazardous Analysis and Critical Control Points (HACCP), limiting inspection where the historic yield of violations is low and where public health risks are negligible.

COMMITTEE DEVOTED CONSIDERABLE ATTENTION TO IMPROVED CONTROL OF MICROBIOLOGICAL AND CHEMICAL CONTAMINATES

In addition, the NAS committee devoted considerable attention to improved control of microbiological and chemical contaminates. These potential health hazards provide unique challenges to USDA and the regulated industry. Microbial and chemical contaminants do not lend themselves to the traditional inspection procedures that rely on physical inspection by sight, smell, and touch. Advanced diagnostic technologies must now be used to make decisions important to public health and safety.

Even though sophisticated detection methods are currently available, in many cases they are too time consuming to allow normal movement of product to the marketplace. Consequently, the industry has increasingly relied on preventative control programs based on sound science and a management commitment to build safety into each critical step of the process. These programs, commonly called HACCP, have become the watchword for process control.

Properly used, HACCP provides an effective tool to produce product in compliance with regulatory standards and significantly greater safety assurance to consumers than exists under current inspection programs. Traditional inspection programs tend to focus on detection and response to problems rather than relying on properly designed prevention programs. Control of critical control points in the production process assures a safe end product and requires only monitoring by inspection personnel.

SUCCESS OF A HACCP PROGRAM DEPENDS ON THE UNDERLYING RESEARCH

The success of a HACCP program depends on the underlying research that identifies critical control points in the process and provides control procedures to determine if standards are met. FSIS has adopted HACCP in principle but has yet to recognize the concept in a general regulatory framework. AMI believes these programs, if more widely adopted, will significantly improve the meat and poultry inspection program.

CONSIDER AN EXPANDED RESEARCH MISSION

To augment scientifically based inspection changes, AMI also strongly urges this subcommittee consider an expanded research mission to support USDA's Food Safety and Inspection Service regulatory objectives.

CONTROLLING MICROBIOLOGICAL CONTAMINATION OF MEAT AND POULTRY PRODUCTS IS A PRIMARY CONCERN

Controlling microbiological contamination of meat and poultry products is a primary concern for USDA and the regulated industry. However, even under optimum conditions, bacteria will be present in the food chain.

Contrary to prevailing public understanding, technical experts familiar with the science of food microbiology know a *zero* tolerance for microbial organisms is unrealistic. Nonetheless, these technical experts also know that properly designed processes and inspection procedures can further reduce exposure to these public health hazards.

COMPLETE ELIMINATION OF ALL MICROBIAL PATHOGENS IS NOT NECESSARY FOR PUBLIC SAFETY

The excellent safety record of meat products suggests that complete elimination of all microbial pathogens is not necessary for public safety. In fact, many microorganisms are beneficial and an absolutely sterile food supply is not a desirable objective. The food manufacturers' objective is to control the growth of pathogenic microorganisms below levels that pose a negligible risk to human health.

The task of defining microbiological criteria for known pathogens is very complex. Nonetheless, USDA and FDA should be commended for undertaking this arduous task through the formation of an expert panel on microbiological criteria. These efforts, with additional epidemiological and analytical research, can provide the basis for more effective food safety regulation.

PREVENT CHEMICAL AND BIOLOGICAL RESIDUES FROM ENTERING THE MEAT AND POULTRY SUPPLY

Preventing chemical and biological residues from entering the meat and poultry supply is the other major food safety concern.

Senator DASCHLE. I need you to summarize, Dr. Marsden.

Dr. MARSDEN. Let me just in one paragraph say that it is important to underscore that everyone in the food chain, including the ultimate consumer, plays an important role in food safety protection. Most foodborne illnesses stem from produce abuse *after* manufacturing. It has been estimated that as much as 97 percent in fact. All of the efforts made by the industry and government inspection can be negated if food distributors, retailers, food service, or consumers improperly store and handle meat and poultry products. AMI believes Federal agencies should strengthen not only their research capabilities but also improve their educational efforts to make food handlers and users more aware of their responsibility to protect the food they distribute or consume.

[The prepared statement of Dr. Marsden and attached report, "A Review of the NAS Study on the Scientific Basis for the Nations Meat and Poultry Inspection Program," appear at the conclusion of the hearing.]

Senator DASCHLE. Thank you, Dr. Marsden.

Let me ask a question just to clarify something you said in your statement.

You said that HACCP is the best response from a policy point of view thus far to microbiological and chemical concerns. Do I take it from that that you are still not satisfied that we can meet the needs for inspection and ensure higher quality of inspection through the use of HACCP alone?

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Dr. MARSDEN. HACCP is the most effective means of achieving food safety because it prevents problems from occurring in the first place. The whole concept of inspecting quality into the products does not work simply because of the overwhelming numbers of animals that are slaughtered for one thing, and the complexity of the task. The way to get it done is to prevent defects, to prevent microbial contamination in the first place.

Senator DASCHLE. So by aggressively implementing HACCP, you think we have responded adequately to the concerns for biological and chemical contamination?

Dr. MARSDEN. Well, I am not saying that we have aggressively pursued HACCP.

Senator DASCHLE. No. But I am saying, had we or would we, you then would be satisfied?

Dr. MARSDEN. Yes, sir. If the objective is to prevent illness from microorganisms or chemical contamination, then I believe that HACCP would be the best way to meet that objective.

Senator DASCHLE. Mr. Carney, do you have any response to that? Is HACCP that good a program?

Mr. CARNEY. From what we have encountered in the field, I feel that it is not sufficient. In my opinion, HACCP is nothing more than drawing a fine line on how much filth, contamination that the public will consume before they become sick. So it may be a quality tool, but I feel that it is not amenable to the food processing industry.

Senator DASCHLE. But Dr. Marsden and others have pointed out, and very persuasively, at least for me, that with the tremendous flow of product and the length of time it takes to test either chemically or microbiologically, you have a real practical limitation to the applicability of other tests to that process. How does one get around that?

Mr. CARNEY. The way that I would see it would be more onsite testing as opposed to an overall method which is what the HACCP system alludes to.

Senator DASCHLE. More organoleptic testing or what?

Mr. CARNEY. No. More scientific testing.

Senator DASCHLE. But that is my point. How do you test scientifically more effectively given the tremendous number of units passing through a plant on any given day? How would you do that?

Mr. CARNEY. That is going to be a tough one to answer. You would just have to have more onsite testing and sampling as opposed to the overall program.

Senator DASCHLE. Let me turn the question around, Dr. Marsden. Is it impossible to devise a way within which one might better utilize microbiological and chemical testing, however good HACCP may be? I mean, frankly I am not as confident that HACCP is the panacea that you might be. I like HACCP, but obviously full implementation of HACCP may never occur. We may never be able to use HACCP to the degree that we might like to. We are going to have to look to other methods.

The impression I have from what you have said—and I may be misinterpreting what you said—is that there really is not a role for microbiological and chemical testing?

Dr. MARSDEN. No, not at all. HACCP is geared toward prevention of defects. There is still some appraisal function or some assessment involved to determine how effective a HACCP program is. So theoretically if the defects are eliminated in the first place, that inspection role is decreased. But there is always going to be some inspection role to make sure that the HACCP principles are operating properly.

There is a good analogy to this, and that is in the automobile industry, where the Japanese do not call it HACCP, they just call it quality management. But they have implemented these principles over a number of years to the point where defects are unexpected events. Their resources are applied to the prevention of defects rather than the detection of defects after they have already happened.

It is not that they do not have any inspection; it is just a difference in the allocation of resources toward prevention rather than assessment.

Senator DASCHLE. I was going to ask the previous panel—we were just getting into it, and for a lot of reasons I wanted to ask some other things so I got off the line of questioning. But, regarding the community's understanding of the acceptable level of microbiological pathogens, do we have an understanding of the tolerance level today? Does the industry agree among itself about what level of microbiological pathogens is acceptable?

Dr. MARSDEN. No. There is a lot of disagreement on that issue. And there is no absolute answer to that because a bacterial infection is a combination of the bacteria itself and the human being that is affected by that bacteria. And the physical health of the individual is just as important as the pathogenicity of the microorganism. In fact, any microorganism that can exist in the human being can cause illness under certain circumstances. Therefore, organisms that are generally considered to be nonpathogenic can under certain circumstances be pathogens.

There are all kinds of examples for this. Dr. Crawford mentioned immunocompromised individuals. And the more immunocompromised an individual is, the less tolerance he would have toward either pathogens, opportunistic pathogens, or microorganisms in general.

Senator DASCHLE. Do we have an understanding about the minimum tolerance level? Obviously there is going to be a tolerance variance. But, is there an agreement in the industry regarding a minimum tolerance level to be applied universally?

Dr. MARSDEN. No. Because, actually, if you wanted to apply a tolerance level universally, you would require a sterile produce. In order for every individual in the population to be able to eat every food product, those food products would have to be sterile. There is, you know, obviously——

Senator DASCHLE. Why would that be? There is a tolerance level in virtually every human being, right?

Dr. MARSDEN. Yes. But that can be depleted.

Senator DASCHLE. So no human being requires sterility in food?

Dr. MARSDEN. No, actually that is not true. Patients who are undergoing chemotherapy, for example, AIDS patients, highly immunocompromised individuals——

Senator DASCHLE. They require a special diet.

Dr. MARSDEN. They require a special diet.

Senator DASCHLE. I am talking about the normal human being, who has a tolerance level that can be defined, can it not?

Dr. MARSDEN. Yes, we strongly believe that. And in fact, a lot of the regulatory process that is going on right now is not geared toward that normal human being. However, it is geared to immunocompromised individuals. And that is exactly what Dr. Crawford was referring to. The fact that there are microorganisms that do not normally cause illness in human beings but can under certain circumstances cause illness. And that microorganisms are being regulated to a zero tolerance.

The industry disagrees with that concept. And that also, by the way, totally disagrees with the HACCP concept, which operates under the principle that pathogenic microorganisms should be controlled below levels which ordinarily cause human illness.

Senator DASCHLE. Mr. Carney, you were talking about the invalidated tests used to detect salmonella and testing methods that are questionable. Can you elaborate, and defend that statement?

Mr. CARNEY. The in-plant laboratories are much more sophisticated for detection than what the tools of the inspector have to use. The plant can take a sample and within 48 hours have a result from their own in-plant laboratories, where we have to take a sample and it may take us 2 to 3 weeks before we can get results back from our certified laboratories. So that was what I was referring to.

Senator DASCHLE. Dr. Marsden, do you disagree with that?

Dr. MARSDEN. No, I do not disagree at all. In fact, that puts the industry also at a disadvantage. When they have to rely on official USDA laboratory results, they are also put at this disadvantage that sometimes it takes 3 weeks or even longer to get results when recognized laboratory results can be obtained in approximately a 48-hour period.

Senator DASCHLE. What reasons are given?

Dr. MARSDEN. The USDA has regional science labs spread out around the United States. They have to receive samples from the inspectors, the samples have to be prepared, frozen, refrigerated, sent to the laboratories. They normally start analyses on Mondays. That is assuming they get to that sample on that particular Monday. And the bureaucratic process just requires more time.

An in-plant laboratory they get the sample immediately. They test the sample immediately and they immediately have the results.

Senator DASCHLE. Dr. Marsden, AMI obviously has made quite a point of opposing the IPI. And I am not sure from your statement exactly what the reasons for opposing it are. Could you again summarize your position with regard to IPI and what you would like to see as it relates to improvements in the plant?

Dr. MARSDEN. The philosophy of IPI, the AMI has always supported. There were some problems, we feel, in the way that IPI was communicated by the USDA which resulted in almost universal displeasure with IPI. But the philosophy that it is based upon, which is a preventative oriented philosophy, the AMI supports and always did support.

We disagree with a few of the details on the implementation. There were some wrinkles in IPI that needed to be ironed out. But fundamentally, philosophically, the AMI supported IPI all along the process.

Senator DASCHLE. You supported it?

Dr. MARSDEN. We supported the concept of IPI.

Senator DASCHLE. The concept?

Dr. MARSDEN. Right.

Senator DASCHLE. But you obviously stated you saw some real problems in the proposal itself. Were they problems that came from your perception of USDA's inability to adequately communicate their proposals to you or——

Dr. MARSDEN. That was part of the reason. There were also some problems with the actual implementation of IPI.

Senator DASCHLE. What were those?

Dr. MARSDEN. The computer system and just, really, details that, in the right climate, I believe could be worked out.

Senator DASCHLE. So in your view there were no substantive problems. The problems were procedural?

Dr. MARSDEN. Procedural, exactly. Procedural and perceived problems.

Senator DASCHLE. Categorically procedural?

Dr. MARSDEN. Excuse me?

Senator DASCHLE. Categorically procedural?

Dr. MARSDEN. I would say so.

Senator DASCHLE. I had failed to ask—that is different from my understanding. If you care to elaborate any more in that regard, I would——

Dr. MARSDEN. To my knowledge IPI and the related improvements, the philosophy that they were based on, the AMI has always supported. And the problem that we had with those programs were more in terms of their implementation and also related in part to the overall misconception that IPI would somehow cause a lesser emphasis on meat safety and take away from the consumer's confidence that meat products are safe.

Senator DASCHLE. I meant to ask one followup question to the last block of questions regarding the tolerance level. If we do not know what tolerance level is acceptable, what are we doing? I do not understand. What if the tolerance level were zero? Obviously it is not. But, how do you gauge the acceptability of product if we have no idea of what the tolerance level ought to be?

Dr. MARSDEN. The subject is unbelievably complex. For example, on salmonella there are 1,800 serotypes of salmonella, ranging from highly virulent to probably totally nonpathogenic, yet there is a zero tolerance for salmonella. I think a lot of it has to do with the ability of the industry to meet requirements, that obviously we want products to be a microbiologically safe as possible.

Senator DASCHLE. But how do you know what safe means? What is the definition of safe?

Dr. MARSDEN. I would say safe is where the level of pathogens in ready-to-eat products approach zero, not necessarily are zero, but controls are in place so that levels are quite low.

Senator DASCHLE. Are quite low, that is a very technical term. Is there not a better way of defining what quite low is? The question

is—you said 97 percent of salmonella comes after the product is purchased—did I understand that?

Dr. MARSDEN. Yes.

Senator DASCHLE. And, that 3 percent of salmonella cases come from the actual processing of the food itself. Is that true with other microbiological diseases as well?

Dr. MARSDEN. Yes, Mr. Chairman, that is generally true. Again, I do not want to hedge on an answer, but it is extremely dependent upon the host individual, the virulence of the serotype involved. And that is one of the problems, I think, that we will always have with microbiological criteria. In fact, the USDA National Advisory Committee on Microbiological Criteria, I would be very surprised if they come up with any specific recommendations on tolerance levels or exact threshold levels for pathogens. They are certainly taking a HACCP approach because that is really the only approach that makes sense.

Senator DASCHLE. Let me ask you this. How do we compare with other countries with regard to microbiological and chemical analysis and the application of technology in inspection today?

Dr. MARSDEN. I would say that if you are talking about Western industrialized countries, that the United States is still probably the leader in food technology and inspection technology.

Senator DASCHLE. Do you agree with that, Mr. Carney?

Mr. CARNEY. No, I do not.

Senator DASCHLE. Who would you say has advanced beyond the United States with regard to this element of inspection?

Mr. CARNEY. European countries.

Senator DASCHLE. Can you give me any corroborating evidence in that regard?

Mr. CARNEY. Nothing other than periodicals that I have read and compared to the European standards as opposed to the substandards that we have here in this country.

Senator DASCHLE. You say the standards in Europe are higher?

Mr. CARNEY. I will attest to that.

Senator DASCHLE. Are they higher, Dr. Marsden, from your point of view?

Dr. MARSDEN. I would say not generally higher. I think there might be some exceptions. For example, the country of Sweden has very stringent microbiological requirements, especially relating to salmonella.

Senator DASCHLE. Let me ask you the same question I asked the last panel in terms of the recommendations. I frankly am still somewhat unclear with regard to whether or not from a policy perspective, either in regulation or in law, we ought to be making any major changes. I sense that there is a requirement from a research perspective, from the point of view of higher scientific and technical personnel, from a number of different perspectives, there is a need. But I do not sense a consensus at all about what that need is.

Mr. Carney, if you could recommend with some specificity two or three specific reforms, what would they be?

Mr. CARNEY. First, I would focus on organoleptic inspection.

Senator DASCHLE. How would you focus on it? What are you talking about?

Mr. CARNEY. More slow on the line speeds down in the slaughter operations, conduct more organoleptic inspection in processing facilities. Plants produce millions of pounds of product a day, and there is never any sampling or oversight as to what goes through this processing procedure. That would be the first.

I would contend that we do need more scientific sampling in the plants. The inspectors need more scientific tools. We are operating out there with clubs and stones right now as far as the scientific aspect. The industry is head and shoulders above us in these plants for conducting scientific inspection.

And the third thing would be funding to put all of this into place. So far, the Agency has not shown any effort to put funding into place. So those would be my recommendations.

Senator DASCHLE. What level of manpower would satisfy you?

Mr. CARNEY. If the Agency would just fill all the vacant positions right now, I think we could adequately handle the inspection needs.

Senator DASCHLE. How many vacancies, in your understanding——

Mr. CARNEY. Well, right now there is a 14 percent vacancy rate across the board with inspectors.

Senator DASCHLE. Fourteen percent vacancy.

Dr. Marsden, do you share that list of recommendations?

Dr. MARSDEN. I would not specifically comment on that. But to comment on your question, I believe that the Agency should take a different philosophical role in inspection.

The law that was passed in 1906 was passed in a completely different atmosphere than what exists today. I agree that the industry probably is scientifically advanced over the Agency, and I believe that in fact if the Agency would take on the role of facilitator versus policeman, that that would best serve the interest of the public. Again, the objective should be to prevent problems, to empower all of the employees in the plant, not just the USDA inspector, but to get everyone involved in producing quality product, in producing safe product, and have the USDA present in the plant as facilitators and to help their process along.

Senator DASCHLE. But that is an attitudinal thing. What in policy or in law would you recommend to bring that about?

Dr. MARSDEN. Well, HACCP-based regulations, that is exactly what they would require. HACCP empowers every individual involved in the process to meet the requirements of the process and thereby produce safe, quality products.

Senator DASCHLE. Are you concerned at all with the 14 percent rate of vacancies in personnel today?

Dr. MARSDEN. I do not have any knowledge to know whether that is in fact the case or not.

Senator DASCHLE. But, obviously, we are not up to 100 percent manpower levels. Is there a concern in the industry about the lack of adequate numbers of inspectors today?

Dr. MARSDEN. Well, if there is a shortage of inspectors, frankly I am not aware of it. But I may not be the best person to sit here and comment on that either.

Senator DASCHLE. What about the availability of resources for scientific research in many of these areas. Are you satisfied that FSIS is providing the necessary allocation of resources to this area?

Dr. MARSDEN. No. I would like to see an increase in efforts toward research, not necessarily research that would have to be done at FSIS, but supporting research. It could be contract research done at universities or private laboratories.

Senator DASCHLE. Would you maintain the current level of organoleptic inspection?

Dr. MARSDEN. Well, that is difficult question to answer. From the scientific point of view, I think the point was made earlier that probably the industry has more at stake in producing quality product than the USDA. And as a result, I think that given the fact that if anything, the requirements of the consumer in terms of quality are always increasing, that I do not believe there is any room any more for producers or processors who cannot produce a quality product.

However, I think that if a change was mandated that lowered the level of organoleptic inspection, I fear that the consumer would perceive that as a very negative thing. From a scientific point of view, I would rather see more emphasis placed on preventing defects that have public health implications.

Mr. CARNEY. Mr. Chairman, could I comment on that?

Senator DASCHLE. Yes, Mr. Carney.

Mr. CARNEY. From an inspector's viewpoint, for what I see with industry, they are more concerned with volume and productivity versus quality. These plants make their money and profit on the amount of tonnage that goes out. In personal dealings with plant management, plant supervision, it is volume and productivity versus quality.

Senator DASCHLE. Let me ask you about the FSIS. One of the fundamental questions I asked the last panel is a question that I am not sure I still have an answer to. Do you think FSIS today has the scientific knowledge and the technological tools to ensure quality inspection?

You are nodding no, Mr. Carney?

Mr. CARNEY. No. FSIS does not have it in place. The training that is capable for the food inspectors right now is very academic as far as scientific knowledge. And while the Agency has just spent a considerable amount of its budget to put it in a new training site at Texas A&M, and today they are still teaching the basic, fundamental inspection tools that we have taught for years. They are not getting into the scientific training. And furthermore, they have not appropriated any scientific tools for us to cope with what the recommendations are right now.

Senator DASCHLE. What about you, Dr. Marsden?

Dr. MARSDEN. I disagree with that. And I have actually had some personal experience in that I taught the USDA training course on one occasion when it was taught at Fort Worth, Texas.

I am not saying that it is perfect, but I would say that they make an attempt to cover a lot of scientific issues. I spend a day and a half on microbiology. I spend a half a day on HACCP. So there certainly is at least some effort to upgrade the scientific expertise at FSIS.

Senator DASCHLE. Well, obviously we are not going to get all the answers this afternoon. And, as I indicated at the beginning, we certainly want to make this an ongoing dialog as we consider our policy options in both regulation and law.

I appreciate both of your contributions this afternoon and testimony as well as the answers to my questions.

I want to be sure that everyone understands we have a record which will be open for at least the next 2 weeks—I should say will be open for a period specifically of 2 additional weeks. If anyone has additional data that they want to submit, the record will remain open for that period of time.

We also may have additional questions to ask of any one of our witnesses. And we will be in contact should those questions arise.

Again, I thank you both, Mr. Carney and Dr. Marsden, for your testimony this afternoon and for helping us in trying to gain a better understanding of this whole issue.

It is a complicated issue, as has been indicated in various ways this afternoon. I believe we have a long way to go. I think that there is a tremendous amount of work with regard to HACCP, with regard to creating more credibility and consumer confidence, with regard to the application of new technology, and I am going to become increasingly involved in this area because of my personal interest as well as my specific responsibilities.

I really do look forward to working with you and our other witnesses to see that we accomplish our tasks.

At this time the hearing is adjourned.

[Whereupon, at 4:36 p.m., the subcommittee adjourned, subject to the call of the Chair.]

[Material submitted for inclusion in the record follows:]

APPENDIX

PREPARED STATEMENT OF THOMAS P. GRUMBLY, PRESIDENT, CLEAN SITES, INC., ALEXANDRIA, VA

My name is Thomas P. Grumbly. I appreciate the opportunity to testify today before this subcommittee in its examination of the Nation's meat and poultry inspection system.

I am currently president of Clean Sites, Inc., a nonprofit corporation dedicated to cleaning up the Nation's abandoned hazardous waste sites. But I appear before you today as a past member of the National Research Council Committee that examined the Scientific Basis of the Nation's Meat and Poultry Inspection Program during 1984 and 1985. Appearing with me today is my colleague from that Committee, Dr. John Bailar. We do not purport to officially represent either the National Academy of Sciences, the National Research Council, or the Committee. The report of the Committee speaks for itself, and I'd ask that the full report be included in the record of this hearing.[1] In the few minutes I have here this morning, I will try to summarize the Committee's findings, particularly as they relate to the necessity for a more "scientific" approach to meat and poultry inspection.

Before undertaking this review, however, the subcommittee should know my own background in these matters in order to better evaluate my testimony. From 1975 through 1987, I was intensively involved in various aspects of the Nation's meat and poultry inspection program. In that time, I had responsibility for overseeing the Nation's program at the White House Office of Management and Budget. I actually helped run the program as its Associate Administrator during the last 2 years of the Carter administration. I examined some of its activities as staff director for the House Committee on Science, Space, and Technology Subcommittee on Investigations and Oversight; I consulted for the program as a management consultant, and finally I worked with two Committees of the National Academy of Sciences as the regulatory and policy expert on groups that were otherwise composed of "hard" scientists. Accordingly, I have seen this program over time from a variety of perspectives. And, as a former senior official in the Agency, I must reasonably share in the blame or praise for any number of policies. I have maintained an abiding interest as an outsider in what most people regard as an arcane area. I have the advantage of knowing the people and the issues, without the disadvantage of being financially dependent on the system or the industry for my livelihood. I don't claim to be right, merely economically disinterested.

From this rather unique vantage point, then, let me first summarize the context for the Academy study, and then lay out its major conclusions, as I saw them.

The 1984-85 Academy study was convened, to use the report's words, because "some of the recent changes in the meat and poultry inspection programs in the United States have been perceived by the public, consumer advocates and inspection staff in the field as compromising human health and safety. Their concern has centered on several issues, including the rate at which slaughtered animals move through inspection, the necessity and efficiency of 100 percent ante mortem and post mortem inspection of groups of animals that seem to be nearly uniformly healthy, the actual health hazard presented by microbial contamination of the meat and poultry supply, and the health effects of low level contamination of meat and poultry by pesticides, drugs and environmental contaminants. Some observers are further concerned that USDA has not adopted newer technologies to provide infor-

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[1] The National Academy of Sciences (NAS) report, "Meat and Poultry Inspection: The Scientific Basis of the Nation's Program," is retained in the subcommittee file.

mation and feedback that could improve the health of livestock and poultry or to address current health hazards, both microbiological and toxic." (Report, p. 18.)

Without going into an elaborate history, the National Research Council's report was the result of more than a decade of rapid change in the environment in which meat and poultry inspection was taking place. In my view, this major change began with the passage of the Wholesome Meat Act of 1967 and the companion Wholesome Poultry Products Act of 1968. Among other things these laws extended meat and poultry inspection to intrastate commerce, mandated that State programs be "equal to" those of the Federal system, and provided financial mechanisms for the Federal Government to take over the inspection programs of States that did not desire to maintain their own programs. A number of States elected, in fact, to turn over their programs to the Federal Government during the late 1960's and 1970's. These take-overs began to put substantial budget pressure on the Federal program, and led to an awakening of interest within both USDA and the Office of Management and Budget about the direction of the program. The concern was spurred by the rather dramatic differences between the nature of the meat and poultry program and the rest of the Nation's food inspection system, operated primarily by the Food and Drug Administration. While FDA was spending $40–$50 million per year to regulate 85 percent of the food supply, USDA was spending four times that to regulate the other 15 percent.

In late 1975, therefore, the Ford administration ordered a major reexamination of the program. The results, of that examination, conducted largely by the national consulting firm of Booz, Allen and Hamilton, were finalized shortly after the Carter administration took office. As the Academy reported later in its findings, that report "found little evidence that many of the (meat and poultry inspection) procedures had measurable public health impact."

While these findings would be debated actively within the Carter administration, and did not form the basis for Assistant Secretary Carol Tucker Foreman's policies, there can be no question but that the rate of change inside the program accelerated during the Carter administration. A toughening of the National Residue Program, an emphasis on the potential problems of food additives in the meat and poultry supply were coupled with fairly large departures in traditional inspection techniques. In 1979, the Meat and Poultry Inspection program began to move toward "Modified Traditional Poultry Inspection," a technique which, among other things, permitted the acceleration of slaughter lines at poultry plants. In 1980, the Agency proposed its long awaited Total Quality Control Program, a fairly radical departure from traditional process inspection techniques, and one whose success depended greatly upon cooperation among the inspection force and selected companies that had exemplary compliance records with the Agency.

The pace of change accelerated further in the Reagan years, as the pressure of budgetary constraints tightened. FSIS contended that any changes would not detract from the public health. Critics among the public interest and inspection communities thought otherwise. In late 1983, then, the late Administrator of FSIS—30-year inspection veteran Donald Houston, a man with an exemplary record of public service—asked the National Research Council to look at the "scientific" basis of the Nation's program. Houston and the NRC reasoned that only by looking at the "facts" underlying the program could one objectively discern whether the critics of the Agency—which included many of its own professionals—were right in their conclusion that the rate of change in the Agency was threatening the wholesomeness of products and the public health.

It is important and appropriate, given the charge to this subcommittee, to underscore that the Academy's charge was to evaluate the "scientific" basis of the Nation's program, *not* to decide whether the inspection service was doing per se a good or a bad job. By *scientific*, I believe the Academy committee came to mean that certain fundamental questions needed to be asked, such as:

1. Did the meat and poultry system have clearly defined objectives that lend themselves to analysis and evaluation?

2. Did the inspection system have the facts, the data, to determine which of the myriad problems it is supposed to address, pose the greatest health risk to the public?

3. Did the inspection system have the information to determine what changes, if enacted, would have the greatest impact on the public health?

4. Did the inspection system have the ability to access the latest biomedical and engineering technologies that affect its ability to do its job?

5. Did the inspection system have access to appropriate levels of research within the USDA and national research system that could help alleviate its problems?

6. Did the inspection system have an adequate number of professionals with the variety of professional and scientific training that is necessary to a modern food inspection system?

7. Did the inspection system have the ability to develop field experiments and evaluations that were found to be credible by the broadest scientific and engineering community of the Nation?

And finally,

8. Did the inspection system expose its findings about change to the fullest discussion within the scientific and public health communities of the Nation?

The Academy committee debated these and other issues strenuously during the 18 months of its existence. FSIS and the rest of USDA cooperated greatly, as did the industry and consumer groups of the Nation. Let me quote the NRC's major overall findings, as well as its particular finding related to meat and poultry processing inspection, and advanced technology—the specific subjects of today's hearing—and then let me paraphrase the Committee's response to some of the specific questions that bear on the "scientific" nature of the problem.

With respect to the overall system, the National Research Council concluded:

"The meat and poultry inspection program of the FSIS has in general been effective in ensuring that apparently healthy animals are slaughtered in clean and sanitary environments. FSIS has made progress in reducing risks to public health from conditions that can be observed during ante mortem and post mortem inspection and that can be evaluated during processing. However, substantial challenges continue to confront the Agency. Some aspects of the inspection system are poorly defined in terms of objectives relevant to public health. A risk-based allocation of resources, supported by modern technology and a systematic evaluation of the program, would be valuable."

Continuing on its evaluation of the processing inspection part of the program, the Committee found that "new (processing) procedures are not likely to diminish protection of the public health. However, the committee could find no clear evidence that the traditional inspection system and modifications to it over the years are based on objectives and criteria that relate to public health. Furthermore, the committee could make no overall assessment of risks and benefits because it could find no comprehensive statement of criteria, no systematic accumulation of data, and no complete technical analysis of the hazards or benefits to human health in the traditional inspection program or as a consequence of the adoption of new techniques" (page 8).

Finally, with respect to the application of new technology, the Committee found that "the efficiency of the current inspection and processing operations, and the ability of those procedures to protect the public health are impeded by the limited application of rapid, specific and sensitive techniques to detect pathogenic organisms and deleterious chemicals in meat and poultry and by inadequate information acquisition and retrieval facilities. For example, the failure to apply sufficiently modern techniques to detect abnormalities in organs and tissues necessitates more extensive, yet less efficient human resources, during inspection."

In examining these conclusions, I am struck again by how careful this committee was in wording its recommendations. We were trying very hard to be constructive, and to give each issue its careful due. But what we were trying to say was really quite simple, in my view: *The meat and poultry inspection system in 1985 lacked the fundamental infrastructure to know whether the changes that were being made were good or bad, and that this lack really inhibited the system's ability to maintain the confidence of the American people.*

Let me examine this conclusion briefly in the context of some of the issues I asked earlier, as they relate to the "scientific" nature of the system.

1. *The problem of objectives.*—It is clear that Congress has given the Agency some tough objectives. We all want our food to be "wholesome" and this definition transcends the definition of public health in ways that are not always easy to define. Accordingly, it is very difficult sometimes to know whether the system is doing well or poorly. Often one is left to the mercy of anecdotal evidence. In a system that involves literally hundreds of thousands of decisions a day, one will always find some localized abuse. But, at least in 1985, it was difficult to know whether, for example, complaints about the impact of changes made by some inspection personnel were typical examples. But the Agency had no way to refute the examples, expect by urging the NRC not to listen to inspector complaints because they were economically self-interested. In short, the Agency had a tendency to refute complaints by innuendo rather than by facts.

2. *The lack of risk assessment.*—In an era in which risk assessment has become commonplace in many public health agencies, FSIS had not shown the inclination

to explicitly assess which of its problems theoretically imposed the greatest health risk on the public. Some individuals, including I might add, most of the members of the NRC committee, believed that microbial contamination was a serious problem, more serious than some of the things that were being looked at more closely. But regardless of view, FSIS had never collected any data that would help it, the Congress, or the American people evaluate the efficacy of where it was putting resources. Accordingly, FSIS could not state, as of 1985, what changes would have the greatest impact, positively or negatively, on public health, if they were enacted. It is my personal view that this lack of evidence is precisely what leaves the Agency and the meat and poultry industry open to so much criticism.

3. *The lack of access to technology and research.*—In our examination, it became clear that FSIS lacks sufficient access to the wider scientific community—particularly the biomedical sciences community. Tied to this it also became clear that the Agency's research needs were often not met within USDA because of competing priorities within the Agricultural Research Service and the Cooperative State Research Service. What needs to be clear is that meat and poultry regulations is *scientific* regulation, i.e., that it needs to be based upon the best data one can develop, and on the development of new technology to deal with some very difficult contamination problems in a production environment.

4. *A lack of adequately skilled technical professionals.*—The committee noted again and again that FSIS did not have sufficient numbers of experts in risk assessment, sampling methodology, and toxicology to handle the increasingly complex nature of problems in the system.

5. *A lack of openness.*—Finally, the committee noted that USDA often developed programs and regulations in a closed fashion, i.e., without extensive debate within the relevant scientific and technical communities, nor with the advice of some of the best people in the academic community. There was a strong belief inside the Committee that FSIS needed to reach out more beyond its traditional veterinary constituencies to the public health community if it wished to have support for major changes in its programs.

The Committee was not led by this analysis to a conclusion that all changes should stop until every problem was corrected. There was the practical realization that life must go on, even as improvements were being made. However, I should tell you that this Committee, composed almost entirely of professionals who were conditioned to accept change, was very frustrated by the lack of information about the potential impact of change. It would not be fair to say that the Committee wanted USDA to be perfect, or that the Committee was too "academic" in its desire for information. The facts are that we saw very little data from USDA that would lead one to believe that the Agency had carefully scoped out, or thoughtfully evaluated, the changes it wanted to make or had already made. FSIS is the quintessential "implementation" agency; that is often its greatest virtue. But, as it undertakes to persuade the scientific establishment, the political community, and the public of its changes, that action orientation can be a hindrance. Others this morning can testify as to the reaction of FSIS since 1985. If, however, the Agency is relying upon the recommendations of the National Academy of Science to justify its changes, I must tell you that the unanimous response of the Committee to any change would be: *Show us the data, or you will not get us to support it, even if we believe you may be right.* In the absence of a concerted effort to address the problems in "scientific infrastructure" found by the Academy, the Agency should not rely upon the Academy study as fundamental support for its decisions.

I understand that this Committee is considering the addition of fish inspection responsibilities to USDA. I would urge that you strongly encourage USDA to reach out to the biomedical research and public health community on issues like microbiological standards before you extend this responsibility. I would also urge that you commission a program of research now on these and other issues, so that our inspection programs can go forward with the maximum amount of support from the health community and from the American people.

Thank you very much, and I would be happy to answer any questions you might have.

STATEMENT OF JOHN C. BAILAR III
DEPARTMENT OF EPIDEMIOLOGY AND BIOSTATISTICS
MCGILL UNIVERSITY

Mr. Chairman and members of the Committee: Thank you for inviting me to present to you the recommendations of two committees of the National Academy of Sciences (NAS) that have examined certain aspects of our nations' programs for inspecting meat and poultry. These recommendations are included here as Appendix I and II, and a statement of characteristics of an optimal meat and poultry inspection program, taken from one of the reports, is included as Appendix III. I was a member of both committees and fully endorse the two reports. However, I am here today only as a private citizen with some interest in and knowledge about the reports. The reports themselves are:

> Meat and Poultry Inspection: The Scientific Basis of the Nation's Program, National Academy Press, 1985
>
> Poultry Inspection: The Basis for a Risk-Assessment Approach, National Academy Press, 1987

Both were prepared at the request of the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA). The second was requested specifically to expand on certain points in the first report as they touched on poultry, especially broiler chickens.

I believe that your committee has had an opportunity to read these two reports and to study the conclusions and recommendations. I will therefore use this statement to explain some of the context in which the reports were written. Their focus was very clearly and specifically on human health including such questions as: What are the human health risks in meat and poultry? How, and how well, do various meat and poultry inspection activities address those risks? How can the health-protection aspects of inspection be enhanced? And what might new technology have to offer?

The meat and poultry inspection program of the FSIS has many goals besides the protection of human health. These include such things as protection of the cleanliness and wholesomeness of meat and poultry parts and products that may reach our tables, protection against economic fraud or mislabeling, and protection of food animals, including poultry, from inhumane slaughter. It is critical that you understand our focus on human health, because some aspects of inspection may be worth preserving or enhancing even though they have little or no relationship to health.

Examples are post-slaughter fractures in poultry, dirt that reaches the exposed surfaces of skinned animals, and mislabeling turkey parts as chicken. None of us want these things to occur, but when there was no probable connection to human health the NAS committees made no comment.

With this narrowed focus, we found only two classes of hazards of real concern: microbial and chemical. Microbial hazards appear to be the more serious. The slaughter and butchering of carcasses are intended to be carried out under quite clean conditions, but they are not surgically sterile. In addition, animals and birds may sometimes harbor microbes deep in their tissues (as do humans). But the presence of microbes does not necessarily indicate any health risk; indeed, any unprocessed food is virtually certain to carry some kind of microbiological contaminant, including fresh fruits and vegetables, milk, eggs, and grains. Human illness occurs only if the microbe reaches the human body in numbers adequate to cause infection, and at a time when biological defense mechanisms are unable to respond to the challenge. With proper slaughter, handling, and distribution; careful food handling in homes and restaurants; and adequate cooking, the microbial risks of meat and poultry to the consumer are close to zero.

Conditions are not always perfect, of course, and one may ask whether traditional "organoleptic" inspection (by sight, touch, and smell) can help to protect the public. The answer is no, not to any appreciable degree. The microbial contamination that leads to human health risks is not sufficient to make slaughtered birds or animals visibly ill (one of the things inspectors look for prior to slaughter), and in most cases makes up only a tiny fraction of the total microbial burden. That burden as a whole is simply not in general detectable by organoleptic inspection. This should not surprise us. The human body, too, is covered with countless microorganisms, some of which are capable of causing disease if they get past the skin, but those microorganisms cannot be seen, or felt, or smelled--and they usually cause no trouble. In summary, traditional organoleptic inspection of freshly slaughtered meat and poultry has almost nothing to do with the protection of human health, though it may have substantial merit for other reasons.

The second class of hazards that meat and poultry may pose to human health is chemical contamination. A wide range of toxic chemicals can be found in our environment, some from natural sources and some produced by humans. Some of these can enter farm animals, primarily by way of their feed and water, and the concentrations of some chemicals may even be increased if the

animal retains a sufficient fraction of the chemical taken in ("bioaccumulation"). Again, however, signs of contamination can rarely be detected by traditional inspection. Specific chemicals may be very toxic, but even after substantial bioaccumulation they are not present in quantities sufficient to be seen, or felt, or smelled, nor do most of them cause evident illness or changes in animal tissues that the inspector can detect.

Both of the NAS committees were much concerned about the protection of human health from microbial and chemical hazards. Similarly, we were concerned about the whole range of inspection activities that are quite adequately justified on grounds other than health. We could not find, however, that traditional organoleptic inspection of each slaughtered animal and bird makes any substantial health contribution. In view of these considerations, we have made numerous suggestions for change, as stated in the two reports and the three appendices to this statement.

FSIS recognized, and we certainly concurred, that no major change in inspection should be made without adequate demonstration that the change was likely to improve protection of health, reduce costs, or both. Our two reports were written to be comprehensive considerations of the scientific underpinnings of meat and poultry inspection. I hope that they provide FSIS, your Committee, and others with the critical basis you need to make reasoned decisions.

In conclusion, I must express may personal admiration for the staff of the FSIS. They have done very well those things they have been asked to do, and the senior management of FSIS has been well aware of the need to bring inspection procedures into line with the real nature of the risks. To their credit, they have asked for substantial advice and comment (not just from the NAS), and I understand that they are implementing those changes that they have authority to make. The present program is already very good, and we can expect it to be better yet in future years. The shifts in goals and resources recommended by the two NAS committees, refined by the special knowledge and experience of FSIS and USDA more generally, will, I believe, provide a useful increment in protection of the public health.

Thank you for this chance to summarize and explain the context of these two reports. I will be glad to respond to questions.

APPENDIX 1

Recommendations. Taken from: Executive Summary, Meat and Poultry Inspection: The Scientific Basis of the Nation's Program. National Academy Press, 1985.

Public Health Risks Related to Biological Agents

Recommendations. The committee recommends that FSIS intensify its current efforts to control and eliminate contamination with microorganisms that cause disease in humans. Such efforts should include evaluation of rapid diagnostic procedures for detecting microorganisms, especially species of Salmonella and Campylobacter, and education of the general public, health care personnel, educators, and extension service workers in the safe handling of meat and poultry. The committee also recommends that meat handling practices in plants be monitored and evaluated in an attempt to prevent the occurrence of meat- and poultry-derived infections among plant employees. Although their prevalance is low, these infections present significant and avoidable occupational hazards. Better epidemiological surveillance and coordination of efforts to eradicate these diseases are also needed. (See Chapters 3, 6, and 7 for a detailed discussion of biological agents in meat and poultry that pose a risk to human health.)

Public Health Risks Related to Chemical Agents

Recommendations. The committee recognizes that the NRP is constrained in many ways by its legislative mandates. It recommends, however, that the NRP strive to make substantial progress in several categories to meet the requirements for an optimal program identified by the committee. In particular, the NRP should incorporate strategies that would prevent consumers from exposure to potential health hazards. One of the ways this could be accomplished is to introduce a system to identify and trace back animals to their farms. The sampling plan to test chemical residues should be revised to improve the confidence level of detection by using appropriate statistical methods and new technological advances. Furthermore, the committee suggests that FSIS reexamine the priorities and the methods used by regulatory agencies for establishing tolerance levels of chemicals to ensure that they appropriately reflect the degree of risks to public health. Formal risk assessment and frequent communication with other regulatory agencies and with scientific peer-review groups would be particularly beneficial to FSIS in this endeavor (see Chapter 4).

Production of Food-Animals

Recommendations. The committee recommends that means be found for FSIS to coordinate the control and monitoring of hazardous agents during production, where those agents enter the food supply. Furthermore, it recommends that a system be developed for keeping track of food-animals during their lifetime, that procedures be instituted to trace residues in samples back to their sources, and that a national center be established to monitor and store information on animal diseases. To assist in these efforts, the committee recommends that all USDA animal disease surveillance programs be designed and implemented to use fully the animal disease prevalence data obtained from meat and poultry inspection programs.

Meat and Poultry Processing and Inspection

Recommendations. Overall, the committee recommends that the precepts of risk assessment (identification of the problem, exposure assessment, hazard assessment, and quantitative health risk assessment) be systematically embodied in the planning and evaluation of all phases of meat and poultry inspection, and that risk-assessment criteria be used regularly to assess consequences to public health of any modifications in the inspection process (see Chapter 10).

Despite its preliminary conclusion based on the limited information that TQC works satisfactorily, the committee recommends that newer technologies be incorporated into TQC and that personnel be recruited and trained to increase the efficiency of the system. As explained below, the committee favors the incorporation of the HACCP approach into meat and poultry slaughtering and processing operations, including the TQC program.

Whereas traditional inspection applies primarily to the ante- and postmortem phases and TQC is currently applied during the processing of meat and poultry, HACCP is a comprehensive approach applicable to the range of operations from production of animals to slaughter, processing, and handling in retail outlets, food-service establishments, and homes. Traditional inspection and TQC are structured to comply with federal inspection regulations, which are concerned to a large extent with plant sanitation and with aesthetics and economy in producing safe and wholesome products. In contrast, HACCP is concerned primarily with criteria relevant to public health.

The committee recognizes that FSIS has implemented the principles of HACCP in certain operations; however, it recommends that those principles be applied more rapidly and comprehensively in plant operations and that periodic evaluations be performed to ensure that critical control points related to public health are emphasized in the inspection process in addition to whatever control points are needed for reasons related to aesthetics and economy. This should apply to both traditional and TQC approaches. To achieve both operational efficiency and protection of public health, critical control points must be identified, inspectors trained in the HACCP approach, and procedures regularly monitored.

Advanced Technology

Recommendations. In the judgment of the committee, the techniques that have the greatest potential applicability to FSIS procedures are imaging techniques, computer-assisted information transfer, and automated laboratory methods for analysis and measurement. To achieve the goal of installing a modern, technology-based system, the committee recommends that FSIS develop a capability for conducting or contracting for scientific and technical research tailored to its needs, rather than depending on other USDA agencies. However, interaction with other USDA agencies, other government agencies, and private groups is essential. Thus, the committee also recommends the establishment of a scientific advisory body composed of representatives from government, industry, universities, and research organizations to facilitate such interaction (see Chapter 9).

APPENDIX 2

Recommendations. Taken from: Executive Summary, Poultry Inspection: The Basis for a Risk Assessment Approach. National Academy Press, 1987.

GENERAL RECOMMENDATIONS

- FSIS should adopt the well-established precepts of risk assessment as an integral part of its strategy to identify and manage public health risks associated with poultry. The committee's risk model can serve as a prototype that FSIS can refine by applying its extensive knowledge of the poultry system.
- FSIS should evaluate the current inspection system by using the risk-assessment model proposed by the committee and on the basis of its findings, modify the system so that it more directly addresses public health concerns.
- Rather than focusing on one procedure, such as bird-by-bird inspection, as the primary component of an inspection process, FSIS should direct its efforts toward the establishment of a comprehensive quality assurance program. Such a program would consist of several components, one of which might be organoleptic inspection.
- Emphasis should be shifted from detection to prevention of problems at the earliest feasible stage in production to increase the effectiveness of poultry risk-management activities.

A RISK-ASSESSMENT MODEL FOR POULTRY-ASSOCIATED HAZARDS

Recommendations

- The committee's risk model should be regarded as a prototype that FSIS can modify and refine to suit its own special needs and goals.
- FSIS should attempt to ensure that all aspects of the poultry system are included in any risk model used, even if certain areas fall within the purview of other agencies.
- Qualitative risk assessments should form the initial bases for planning and selecting inspection and quality assurance programs. Quantitative assessments should be used when qualitative assessments prove inadequate and when sufficient data are available.

MICROBIOLOGICAL HAZARDS AND POULTRY

Recommendations

The association between microorganisms in and on poultry at slaughter and the occurrence of disease in humans is complex. Several potential sources of contamination exist throughout the poultry system. The committee recognizes, therefore, that attempts to resolve this problem will be correspondingly difficult and may require collaboration with other agencies. On the basis of its review of the literature and established principles of microbiology, however, the committee recommends that certain actions such as the following be taken to reduce the potential for disease to be caused by poultry-borne microorganisms.

- The ongoing search for data on microbial risks should continue and be complemented by new research. Emphasis should be placed on the prevention of human disease rather than on simple control of microbial counts during slaughter and processing.

- Potentially pathogenic microorganisms on poultry should be identified, the potential for exposure to an infectious dose of each pathogen should be determined, and the potential impact on public health that would result from the failure to control exposures should be evaluated.
- The critical control points at which known pathogenic microorganisms such as Salmonella and Campylobacter may be introduced into the poultry system should be identified and monitored, preferably as a part of an HACCP (Hazard Analysis Critical Control Point) program.
- A population-based surveillance program should be established so that disease occurrence can be correlated with inspection strategies. This will require measuring the level of pathogenic microorganisms on market-ready poultry as well as establishing a system for surveillence of disease within a well-defined population.
- A range of educational programs for people who raise poultry and for those who handle raw broilers in slaughterhouses, at retail, and during food preparation in the home and commercial establishments should be developed or intensified. As part of this effort, poultry products should be labeled at retail to inform consumers how to handle the poultry to prevent diseases originating from microbial contaminants.

CHEMICAL HAZARDS AND POULTRY

Recommendations

The committee's major recommendations regarding chemical residues are based on its observation that important sources of residues are not considered in the FSIS monitoring program and that priorities for risk management are currently not set according to the relative magnitude of risk for known residues. If adopted by FSIS, the following recommendations should result in distinct improvements in the residue program:

- Using degree of risk as a basis, FSIS should establish priorities for monitoring residues and associated activities.
- Potentially hazardous chemical residues in poultry and their points of origin should be identified.
- The risks associated with identified hazardous residues should be determined.
- Using known risks as a basis, FSIS in collaboration with EPA and FDA should ensure that tolerance levels are set for known hazardous residues.
- Control programs to monitor the entry of residues into poultry should be developed.
- FSIS should determine how chemically contaminated poultry might be removed from the marketplace or production line.

CURRENT FSIS PROGRAMS AND STATISTICALLY BASED SAMPLING

Recommendations

- FSIS should begin to lay the groundwork for shifting resources from the organoleptic inspection of each broiler chicken to a more comprehensive program with statistically based sampling as one of its primary features. This should be undertaken as a first step in modifying the traditional bird-by-bird inspection system.
- FSIS should shift the focus of its residue program from the detection of contaminants in market-ready products to the prevention of their introduction at points as early as possible in the production process.

- An adequate sampling plan, designed to protect the consumer from exposure to chemicals that are not randomly distributed across the country.

- Emphasis on hazard analysis and critical control points (HACCP), limiting inspection where the historic yield of violations is low and where public health risks are negligible.

- Documented assurance, backed by substantial compliance enforcement, of the sanitary wholesomeness of all meat and poultry products.

- Enhanced enforcement capability to impose a broad range of penalties upon violators, including refusal to inspect and approve their products.

- Adequate resources to ensure continued improvement of the technological base of FSIS, including the development of new inspection technologies to reduce cross-contamination of carcasses and more comprehensive assessment of toxicological hazards.

- A mandatory system of initial and continuing education for inspection personnel that emphasizes food science, food technology, pathology, and public health, combined with a recertification program.

- A substantial scientific and technical FSIS staff of respected scientists who play a substantial consultative role in the development of policy.

- The presence of standing advisory panels composed primarily of outside experts to provide consultation on both policy and practice regarding meat and poultry safety. Disciplines represented on these panels should include food science and technology, computer applications, microbiology, biostatistics, epidemiology, veterinary medicine, toxicology, systems analysis, animal health, economics, marketing, nutrition, and risk analysis. Again, no one discipline should dominate any panel. All major regulatory proposals should be reviewed by standing advisory panels prior to finalization.

- Strong liaison between FSIS, CDC, the Food and Drug Administration, and relevant animal health agencies at the federal, state, and local levels to ensure that no hazards are overlooked.

- Substantial use of a rapid, timely, and flexible system (probably computer-based) to acquire, transfer, analyze, and make more widely available data related to inspection and to meat-borne hazards.

APPENDIX 3

Characteristics of an Optimal Meat and Poultry Inspection Program. Taken from: Executive Summary, Meat and Poultry Inspection: The Scientific Basis of the Nation's Program. National Academy Press, 1985.

CHARACTERISTICS OF AN OPTIMAL MEAT AND POULTRY INSPECTION PROGRAM

In view of the above conclusions and recommendations, the committee identified the following components (not in any order of priority) of an optimal meat and poultry inspection system. It recognizes that many of these components are part of the current FSIS system (see Chapter 10).

- A trace-back and recall system from final sale to producer for all animals and products destined to enter the human food supply. This is essential for the generation of data that are important to the prevention of disease in humans and that will enable processors and the government to solve problems in the food chain.

- Maximum use of plant personnel in process-by-process and day-to-day monitoring of critical control points, and FSIS oversight to ensure compliance.

- Use in all phases of inspection of a technically qualified team with up-to-date knowledge of veterinary medicine, food science, public health, food engineering, food technology, epidemiology, pathology, toxicology, microbiology, animal science, risk analysis, systems analysis, statistics, computer science, and economics. Similarly, managers should have expertise in several relevant disciplines, including veterinary medicine, food science and technology, nutrition, public health, and public management. No one discipline should dominate management.

- An inspection system with different levels of intensity, reflecting the degree of public health risk at various stages in the process, the reliability of the monitoring system, the compliance history of the slaughterhouse or processing plant, and the special needs of the intended consumer (e.g., military personnel and schoolchildren).

- Development of a list of the diseases that can be identified by each step in the inspection procedure. This list should be used to determine whether the steps are useful for protecting human or animal health, useful for detecting aesthetically objectionable conditions, necessary to protect consumers against fraud, or able to provide other identifiable benefits.

- Random sampling of retained or condemned carcasses and parts of carcasses in order to develop definitive diagnoses. These diagnoses can be used to establish baseline data on etiologies associated with each condemnation category and to provide material for pathology correlation sessions as continuing education for in-plant veterinary medical officers.

- Rapid, inexpensive screening tests to detect a broad array of chemical compounds and biological products that may be hazardous to the consumer.

- Federal government support of broiler chicken inspection and related activities should be allocated primarily according to the degree that it can contribute to reductions in public health risk. The current postmortem poultry inspection system does not address or meet this objective.
- A shift in the focus of FSIS programs toward the identification of contamination sources would necessarily extend the agency's interests to areas that are now the responsibility of other government (including state and local) agencies. FSIS should attempt to persuade such agencies that closer communication regarding poultry-associated health hazards is a matter of primary importance and that their effective control will require a concerted effort among responsible authorities.

STATEMENT OF MICHAEL M. PULLEN, D.V.M., PROFESSOR/ EXTENSION MEAT HYGIENIST, COLLEGE OF VETERINARY MEDICINE, UNIVERSITY OF MINNESOTA

July 20, 1989

Mr. Chairman, members of the Subcommittee, thank you for the invitation to present testimony to the Senate Agriculture Committee's Agricultural Research/General Legislation Subcommittee. My comments are based on observations following service on both National Academy of Sciences (NAS) Committees reporting on the USDA, Food Safety and Inspection Service (FSIS), Meat and Poultry Inspection Program. Two reports contracted for by FSIS were issued by the National Academy of Sciences: 1) Meat and Poultry Inspection: The Scientific Basis of the Nation's Program (1985) and 2) Poultry Inspection: The Basis for a Risk-Assessment Approach (1987). Following the testimony of two other fellow NAS Committee members, I have been asked to comment on and to assess the progress of FSIS on several key NAS recommendations.

The specific Subcommittee concerns that I will address are:

1) How much progress has FSIS made to date in developing and using rapid diagnostic procedures for pathogenic microorganisms?
2) How important are rapid diagnostic procedures to reducing threats to human health from meat consumption?
3) With regard to health risks from chemical agents, the NAS Committee recommended that FSIS revise their sampling plan in testing for chemicals residues to improve the confidence level of detection by using appropriate statistical methods and new technological advances. To what extent has FSIS implemented these suggestions?
4) To what extent has FSIS identified critical control points and implemented HACCP?
5) How much progress has FSIS made toward the development and use of "rapid, specific, and sensitive techniques to detect pathogenic microorganisms and deleterious chemicals in meat and poultry"?

In terms of the specific characteristics of an optimal meat and poultry inspection program, the Chairman has requested my assessment of the extent to which current or planned FSIS inspection procedures embody the following:

* Rapid, inexpensive screening tests to detect a broad array of chemical compounds and biological products that may be hazardous to the consumer.
* An adequate sampling plan designed to protect consumers from exposure to chemicals that are not randomly distributed across the country.

* Adequate resources to ensure continued improvement of the technological base of FSIS, including the development of new inspection technologies to reduce cross contamination of carcasses and more comprehensive assessment of toxicological hazards.
* A mandatory system of initial and continuing education for inspection personnel that emphasis food science, food technology and public health.
* A substantial scientific and technical FSIS staff of respected scientists who play a substantial consultative role in the development of policy.

Rapid Diagnostic Tests - Pathogenic Microorganisms

FSIS has a highly respected Microbiology Division, Science. This staff routinely monitors meat/poultry products for microbial pathogens. Their emphasis, and rightfully so, has been directed towards pathogenic organisms that might be present in ready-to-eat meat/poultry containing products. Since ready-to-eat products may not be heat treated prior to consumption, these products if contaminated with pathogenic organisms could serve as a ready source of food borne illness. Examples of these pathogens include: Salmonella in pre-cooked roast beef, Listeria in pre-cooked sausage products, Staphylococcal aureus in ready-to-eat meat/poultry products. As it relates to raw meat and poultry products, progress has been less rapid. Although rapid isolation/identification procedures have been reported for Salmonella from raw meat/poultry products, FSIS must proceed slowing in accepting them since they may not meet the regulatory requirements of the Agency.

Rapid diagnostic procedures for pathogenic microorganisms are extremely important in implementing the HACCP approach. These procedures would enable the federal establishment to identify their critical control points (CCP) for pathogenic microorganisms, establish effective controls and then utilizing rapid, diagnostic procedures, monitor the success of their HACCP program. More importantly, these rapid, diagnostic procedures could enable the FSIS, Microbiology laboratories to screen more meat/poultry samples for pathogenic microorganisms, thus assuring compliance of various federal establishments CCP's for meat/poultry products.

Sampling Plan - Chemical Agents

Presently, residue monitoring is achieved by taking random samples of tissue from apparently healthy domestic meat and poultry animals as they pass through routine inspection at slaughter and random samples of imported meat products. In general, the number of samples tested is designed to ensure, at the 95% confidence level, that the chemical will be detected in at least one sample if it occurs in 1% or more of the population of animals being observed during a given year. Approximately 100 chemicals are sampled for annually. Because of the increasing number and variety of contaminating residues that may constitute possible health hazards, especially to susceptible subgroups in the population, and because the overall contamination rate of less than 1%

may be considerably higher for certain food sources or consumer groups, the NAS Committee questioned whether the size of the sampling plan was adequate.

The NAS Committee concluded that the most effective way to prevent or minimize hazards presented by certain infectious agents and chemical residues in meat and poultry is to control these agents at their point of entry into the food chain, i.e., during the production phase on the farm and in feedlots. The NAS Committee quickly recognized that FSIS could not exercise such control because it has no jurisdiction in those areas.

A successful residue program includes: 1) animal identification; 2) quality control programs on farms/feedlots; and 3) rapid, accurate tests for farm screening and in-plant screening of more tissue samples.

FSIS has implemented the swab test on premise (STOP) test for certain antimicrobial agents. This test developed by the FSIS Microbiology Division enables the inspection program to rapidly screen suspect animals, including poultry for antimicrobial residues. The STOP test was later modified for use on farms for screening animals prior to shipment for slaughter: it is called the Live Animal Swab Test (LAST). In addition, the Chemistry Division, FSIS developed a thin-layer chromatography test for screening swine urine, as well as feed/water samples, for sulfamethazine. The sulfa-on-site (SOS) test is designed for use in both the federal hog slaughtering establishment and on the farm for screening hogs for violative sulfamethazine levels. The SOS test has been instrumental in reducing violative levels of swine sulfamethazine from 4-6% to less than 0.6% in one year. FSIS is currently evaluating a card test to screen samples for chloramphenicol. The card test is extremely sensitive and rapid. Progress is being made in the introduction of new, rapid, sensitive tests for chemical residues to be utilized both in the federal establishment and on the farm. These rapid, inexpensive tests enable the livestock producer to routinely test samples of animals before slaughter to verify production control programs. It is envisioned that such a production control program could involve many chemicals on many farms throughout the U.S. Progress is being made.

Hazard Analysis Critical Control Point (HACCP) Approach

The Hazard Analysis Critical Control Point (HACCP) System was introduced in 1971 and HACCP provides a more specific and critical approach to the control of microbiological and chemical hazards in foods than that provided by traditional inspection and quality control approaches. The system has three procedures: 1) identification and assessment of hazards associated with growing, harvesting, processing, marketing, preparation and use of given raw materials or food product; 2) determination of critical control points to control any identifiable hazard; and 3) establishment of systems to monitor critical control points. HACCP, when properly applied, separates the essential from the superfluous aspects of hazard control by focusing attention on those points that directly affect safety and quality and by monitoring to determine whether or not these points are under control.

In the 1985 NAS report, HACCP was identified as a comprehensive approach applicable to the range of operations from production of animals to

slaughter, processing, and handling in retail outlets, food service establishments, and homes. HACCP is concerned primarily with criteria relevant to public health. The NAS Committee further recognized that in order to achieve both operational efficiency and the protection of public health, critical control points must be identified, food inspectors trained in the HACCP approach, and procedures regularly monitored.

FSIS certainly recognizes the importance of the HACCP approach but has been slow in implementing it. Each federal establishment should have its own HACCP system based on the public health hazards that may be involved. Presently, a Puerto Rico study on poultry slaughter is being conducted to determine the critical control points for Salmonella. I am serving as one of five outside consultants on the project. Data collected should enable FSIS to provide guidance to poultry slaughtering establishments in controlling microbial hazards, particularly Salmonella.

Detection Methods - Pathogenic Microorganisms/Chemicals

As previously mentioned, FSIS has devoted a great deal of time and resources for developing detection methods for pathogenic microorganisms and chemicals. Their successes have been noteworthy and include CAST, STOP, SOS, LAST, as it relates to antimicrobial agents. Improved detection methods for pathogenic microorganisms has been slower. FSIS developed the mechanized enzyme labelled antibody test that is being utilized in a North Carolina swine slaughtering establishment for the detection of Trichinella spiralis. Success in the development of rapid, dependable detection procedures is very slow. Continual effort is being made and it is a high priority for both FDA and FSIS.

Summary

My assessment of FSIS progress since the release of the 1985 NAS report in specified areas are:

* The development of rapid, inexpensive screening tests to detect a broad array of chemical compounds and biological products that may be hazardous to the consumers has been very slow. However, FSIS should be commended for its successes and its continued emphasis in developing tests.
* An adequate sampling plan, designed to protect consumers from exposure to chemicals that are not randomly distributed across the U.S. A truly successful program would embody the HACCP approach with control directed at the farm level. Such a HACCP program would require animal identification back to the farm of origin; a certification/verified production program and routine monitoring of animals at slaughter for compliance. Because of the various federal/state agencies involved progress is this area has been painfully slow. A most recent commendable FSIS success has been the SOS test implementation and dramatic reduction in per cent violations for sulfamethazine in swine.

* As previously mentioned FSIS strongly endorses the HACCP concept but has been slow in implementing it. Improvement could be made in this area particularly in processed meat/poultry products.
* A mandatory system of initial and continuing education for inspection personnel that emphasizes food science, food technology and public health. Food inspectors have been encouraged to participate in self-study courses and/or attend classes to improve their expertise in these areas. Veterinary Medical Officers can attend night courses with tuition paid by FSIS. Several VMO's have received Masters in Public Health (MPH) degrees from the John Hopkins University utilizing this protocol. In addition, the University of Georgia has provided graduate training opportunities and degrees to a number of VMO's. More recently, the FSIS contract with Texas A & M for the Don Houston Meat/Poultry Inspection Training Center will provide excellent educational opportunities. Significant progress is being made.
* A substantial scientific and technical FSIS staff of respected scientists who play a substantial consultative role in the development of policy. FSIS has a number of outstanding individuals that meet this need. However, significant additional numbers are required due to retirements and unmet needs. In their hiring process and educational opportunities, FSIS is adding new members to its scientific cadre. Utilizing advisory committees, i.e., Meat/Poultry Inspection Advisory Committee, Microbiology Advisory Committee and consulting groups (i.e., Puerto Rico Project), FSIS continues to enhance its scientific/technical expertise. It is envisioned that combinations of the above will be required to continue to address FSIS's scientific/technical requirements.

PREPARED STATEMENT OF JO ANN R. SMITH, ASSISTANT SECRETARY, MARKETING AND INSPECTION SERVICES, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC

Mr. Chairman, as the Assistant Secretary of Agriculture for Marketing and Inspection Services, I appreciate the opportunity to appear before this subcommittee exploring the scientific and technical capabilities of the Food Safety and Inspection Service. I will present an overview of our plans, and Dr. Lester M. Crawford, FSIS Administrator, will provide more specific details.

Modernization of Federal meat and poultry inspection over the last 15 years has moved the program closer to the optimal inspection system suggested in the 1985 report of the National Academy of Sciences (NAS): "Meat and Poultry Inspection: The Scientific Basis of the Nation's Program." This administration is committed to progress in meat and poultry inspection, and we will continue to modernize the program in keeping with good science. We need to pursue research initiatives that will enhance inspection modernization. We also need to more clearly communicate our objectives and the scientific basis for our actions.

During the 83-year history of the meat inspection law, the industry has evolved from simple, localized and primarily slaughtering operations, to high-tech, high-volume production. Much of today's output is from processing operations producing a wide variety of products in excess of 150 billion pounds annually. In the 1950's, poultry inspection became mandatory. USDA adjusted to this new responsibility, and continues to react to this rapidly expanding segment of the industry.

The industry prospered by developing new technology, and the inspection program has systematically adapted to these changes. As new science becomes available, it is incorporated, making today's program the best it can be. The challenge now is to adjust to changing public health risks. In earlier days, disease detection was the primary focus of inspection. Today, the primary risks are unseen hazards, which require a modern laboratory capability as well as in-plant inspectors. This is the area where research initiatives are most needed.

The inspection program has compiled an enviable record, aided by capable leadership, which, the 1985 NAS report noted, exhibits a "willingness to make changes and to act on the basis of scientific and technical evidence." Systematic planning processes have set program objectives and established guideposts for modernization initiatives. However, as Dr. Crawford will elaborate to you, we have not unlocked all the secrets, and further research is imperative. The reduction of risk from microbiologlcal and chemical contamination is our most pressing need. We need, first, to expand our knowledge—to better understand the source, mode of transmission and methods of controlling pathogens. We need to be able to identify and accurately quantify long-term chronic effects of potential chemical hazards. We also need to improve our detection methods by adding more rapid, automated, and cost-effective detection methods to those already in use in plants and laboratories. We need more analytical methods for chemicals, particularly multiresidue tests.

IMPROVED COMMUNICATION

We are confident in the safety and quality of our food supply and in the soundness of actions taken to date to modernize inspection, and we feel this confidence is shared in the scientific community. It is not enough, however, to use the best science and to make the right judgments if the public does not have confidence in our actions. We need to improve the public's understanding of the rationale and scientific basis of the inspection program, and we intend to do this.

This includes educating the public about risk. Risk communication is a two-way street. Analysis of public reaction to perceived and real risks helps policymakers understand why people judge certain risks as they do, and that aids in decisionmaking. Our goal is full and open communication about relative hazards, providing the public the opportunity to make informed, rational decisions.

Communication will also enhance our ability to improve inspection. Modernization has too often been equated with reducing the inspection force, substituting computers for inspectors, and turning over the government's responsibilities to the industry. These misconceptions illustrate that although inspection initiatives are sound and supportable by science, the public needs to more clearly understand our objectives if it is to endorse our actions.

Our message is this: a modern inspection program is a better, tougher inspection program because it focuses on the true risks to the public and the true problem plants. We are committed to maintaining the current employment level in the inspection force. The strict inspection standards and the authority of the inspectors have, in no way, been diminished. We have made it clear to processing inspectors that food safety requires that they continue to use their experience and individual

judgment in making inspection decisions. The primary objective of meat and poultry inspection is protection of the public health; every action we take supports that objective.

Food Safety in USDA

Secretary Yeutter has set the tone for USDA saying he will devote more personal time to food safety than have his predecessors because the subject demands it. The Department is a member of the White House Domestic Policy Council's Task Force on food safety and is involved in interagency discussions with the Food and Drug Administration and the Environmental Protection Agency to address the need for a coordinated governmentwide approach to food safety problems.

Research is vital in continuing to maintain the world's safest food supply. USDA's research and education activities are conducted through the Agricultural Research Service (ARS), Cooperative State Research Service (CSRS), Economic Research Service (ERS), and the Cooperative Extension Service (CES). ARS is the primary research arm for the meat and poultry inspection program, and in the current fiscal year the Agency is devoting $13.0 million to food safety research, a $4.5 million increase over the previous year.

Conclusion

Research is the key to maintaining an effective inspection program, and I appreciate the subcommittee's interest in hearing from USDA as you prepare for upcoming legislation. Dr. Crawford will tell you in more detail about the research that FSIS seeks. We are impressed with work ongoing in the private sector, and I hope you will lend encouragement to these efforts as well.

USDA is committed to a strong partnership with our employees, the public and the industry as we continue to pursue the initiatives necessary for maintaining a strong food protection program. We are opening the lines of communication to seek wider comment on our policies because it will enhance our knowledge and the public's confidence in the program.

Statement by
Lester M. Crawford
Administrator, Food Safety and Inspection Service
Before the
Agricultural Research and General Legislation
Subcommittee
of the
Committee on Agriculture, Nutrition and Forestry
United States Senate

July 20, 1989

Thank you, Mr. Chairman. I welcome the opportunity to discuss the scientific and technological readiness of the Food Safety and Inspection Service to implement reforms in the domestic inspection program, as well as food safety research needs for the future. We are proud of the Agency's accomplishments in modernizing inspection, thanks to the continued support of Congress and the Administration for this critical mission of public health protection through food safety.

At the same time, I must emphasize that FSIS does not believe that we have yet developed the optimal inspection program.

In fact, the optimal program will always be just around the corner. As quickly as we incorporate new science and technology to deal with identified public health concerns, new concerns will emerge. Scientific solutions or responses often lag only shortly behind problem definition, but it requires much time and effort to implement improvements in a nationwide program employing seven thousand or more inspectors, food scientists, and enforcement officers. Our challenge will always be to effectively manage a good program based on science and technology, while continually implementing carefully evaluated modifications that will make the program even stronger. We realize we cannot do this with inadequate personnel, and we have no intentions of reducing our inspection work force.

At the turn of the century, wormy, diseased, or spoiled meat was the focus of inspection. Today, our primary concerns are microbiological and chemical contamination.

Many consumers see these public health concerns as public health hazards. This year, the "Trends" survey of the Food Marketing Institute shows that 82 percent of the public view as a "serious hazard" residues such as pesticides. Sixty-one percent feel the same way about antibiotics in livestock and poultry. Responses to a question new this year show that only 23 percent of American shoppers are completely confident about the safety of the food in their supermarket.

Of those who are not completely confident, the greatest perceived threats to the safety of the food they eat are spoilage and germs, tampering, and improper packaging/canning.

The U.S. food protection network, including federal, state, and local health agencies, is here to prevent public health concerns from becoming public health hazards, and it has been very effective. However, we have not been entirely effective; some Americans appear to have questions about the safety of our food supply and the ability of government to verify safety.

Over the coming weeks and months, FSIS will be working closely with Assistant Secretary Smith and other agencies to communicate more effectively about food safety. We must be able to clearly answer the questions of those who are so concerned. We will work toward a shared understanding of the risks in the food supply, their public health significance, and the appropriate control measures to reduce risk.

We must openly explain the effectiveness of FSIS inspection and other regulatory programs in reducing risks and fully discuss how proposed changes will enhance safety.

FSIS ACCOMPLISHMENTS

I will now summarize the scientific and technological readiness of the Food Safety and Inspection Service. In the late 1970's and early 1980's, FSIS began a major modernization initiative to improve the efficiency of inspection, and to infuse more science and better technology into a program that had changed little in this century.

Senior management came to realize that an objective, impartial review of the program would help the Agency shape its plans for the future. In 1983, FSIS contracted with the National Academy of Sciences (NAS) for an evaluation of the scientific basis for inspection; an analysis of different inspection strategies, including

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comparative risk assessment; and for recommendations -- based on new developments in biological research and technology and in food science -- that might be used to further enhance effectiveness and efficiency while maintaining or improving the current degree of public health protection.

This review was a significant effort to draw on the expertise of the external scientific community in improving the public health effectiveness of the program.

The NAS committee on the scientific basis of the nation's meat and poultry inspection program undertook an exhaustive review of the program, including a widely advertised public hearing for submission of oral and written comments and documents.

The committee's report concluded FSIS had been carrying out its mission, noting the Agency

> "has in general been effective in ensuring that apparently healthy animals are slaughtered in clean and sanitary environments," and

> "has made progress in reducing risks to public health from conditions that can be observed during antemortem and postmortem inspection and that can be evaluated during processing."

However, the committee also suggested that perhaps the program could be improved. Specifically, the report observed,

> "some aspects of the inspection system are poorly defined in terms of objectives relevant to public health."

The Committee made recommendations in five broad areas:
public health risks related to biological agents; risks related to chemical agents; production of food animals; meat and poultry processing and inspection; and advanced technology.

The committee also described 17 characteristics of an optimal inspection system. The NAS committee, noting that many of these components were already part of the current FSIS system, encouraged FSIS to compare its program with these criteria and establish a schedule for incorporating missing components "as soon as feasible."

That is precisely what we have done and continue to do. In 1986, FSIS published its response to the NAS report in the form of an agenda for the future. The Agency's Strategic Plan is founded on six organizational objectives which express the overall philosophy and guiding principles of the FSIS meat and poultry inspection program. The six FSIS organizational objectives are:

- PUBLIC PROTECTION
- RISK-BASED ALLOCATION OF RESOURCES
- USE OF ADVANCED SCIENCE AND TECHNOLOGY
- SHARED RESPONSIBILITY WITH INDUSTRY
- ENHANCED ENFORCEMENT
- MORE EFFICIENT HUMAN RESOURCE UTILIZATION

Earlier this year, the Agency published a long-range plan for 1989-93. Both of these documents summarize Agency

accomplishments and plans with reference to the 1985 NAS report and the 1987 NAS report on poultry inspection. I will describe FSIS accomplishments under three general categories: microbial risks, chemical risks, and inspection modernization. From time to time, I will make reference to the NAS recommendations and characteristics of an optimal inspection program, several of which are of particular interest to this Subcommittee.

I believe it will be evident that we have proceeded cautiously and deliberately to build a more scientific program in workable increments. Of course, we remain open to the suggestions of the public and the Congress.

PUBLIC HEALTH RISKS RELATED TO BIOLOGICAL AGENTS

Ten years ago, in Food Safety: Where Are We? (a report prepared for the Senate Committee on Agriculture and Forestry) foodborne illness was recognized as the most significant public health risk associated with food.

Since 1981, microbial contamination has been our number one research priority. In 1985, the National Academy of Sciences recommended that FSIS intensify its efforts in the area of microbiological contamination, including more use of rapid tests and education of targeted groups. Now, we have done much
to build this public health priority into our program functions.

Tests. FSIS has more than tripled the volume of microbiological testing in the last eight years. In 1980, the inspection program analyzed only 10,500 samples in its food microbiology program.

Last year, FSIS analyzed 37,000 samples in its microbiological monitoring and surveillance program.

The Agency has also broadened the scope of microbiological control to cover additional hazards. It has come to be recognized that the contaminant Listeria monocytogenes is widespread in many food-processing environments. FSIS developed an internationally recognized test for Listeria, which is used in our microbiological monitoring program.

FSIS scientists also developed another internationally recognized test to recover and identify Yersinia enterocolitica. This bacteria is not yet a household word, but we are very concerned about it because of its ability to multiply at refrigeration temperatures, as Listeria does. Fortunately, it is not of immediate concern in meat and poultry.

Our scientists have also developed a rapid ELISA (Enzyme-linked immunoabsorbent assay) test for types A, B, and E clostridium botulinum toxins that minimizes the need for more costly animal testing. They have modified a method to rapidly count Escherichia coli, a marker of fecal contamination, in meat and poultry. The Food and Drug Administration (FDA) has shared with FSIS a DNA test that detects the toxin of a virulent strain, E. coli 0157:H7, which has on rare occasions been associated with undercooked beef.

Rapid testing in the microbiological arena is a clear research priority, and FSIS has instituted a program to review new tests that are suitable for regulatory purposes. However, "rapid" is a relative term. FSIS is continually seeking to improve test quality and shorten the time required. For example, a new "reverse passive latex agglutination (RPLA)" test from Japan for Staphylococcal enterotoxin (one of the most common causes of foodborne illness), requires 6 to 8 hours. It replaces one that took 2 to 4 weeks.

If our pace in implementing new tests sometimes seems slow, it must be remembered the scientific process requires exhaustive care in "inventing," verifying, and implementing analytical methods.

It should also be noted that testing is a management tool, not primarily a disciplinary tool. Most emphatically, it should not be the sole means for system control. In educational environments, test results are one indicator of actual learning -- the goal of education. Tests are usually administered at intervals throughout the coursework, so that teachers and students can identify and correct gaps in knowledge by the time the course is over.

In the regulatory environment, the most effective control is accomplished by preventing problems, not simply "catching" products of a failed process.

NAS recommended that FSIS adopt a Hazard Analysis Critical Control Point (HACCP) system for inspection. The HACCP principle is to control each of the control points in the process at which loss of control would mean that a potentially hazardous finished product could result.

In applying a HACCP-type approach to our responsibilities, we have identified some areas for work in microbiology. New canning regulations and handling requirements for cooked and roast beef were implemented in the early 1980's. They require manufacturers to monitor critical control points, set specific requirements for process controls such as cooking, cooling, and handling; and specify strict actions for process deviations.

Currently, FSIS is focusing attention on a broad array of cooked and ready-to-eat products. Cross-contamination between raw and cooked products, long recognized as a critical control point, is one of our major concerns.

We are developing processing requirements according to the HACCP "systems" approach for fermented sausages, cooked patties, dry cured bacon, and other products which pose unique concerns. We have made a substantial commitment to incorporating HACCP-based concepts into our requirements, and we will continue to do so.

A model regulatory program for microbial contamination. The listeriosis outbreak associated with soft cheese was the first confirmed to be linked with a

food of animal origin. Nevertheless, FSIS knew we could not assume meat or poultry to be invulnerable. The Agency promptly began joint efforts to develop an analytical method suitable for meat and poultry, to develop a monitoring scheme, to identify research needs, and to garner the full attention and cooperation of industry.

Our actions were effective. By the time a case of listeriosis was scientifically linked to consumption of a contaminated meat or poultry product, FSIS had a record of evaluating raw products for two years and processed products for a year and a half, while steadily expanding the scope of products included based on risk assessment. When we learned of the association with a meat product some months after it actually occurred, we were able to quickly redefine our regulatory program on the basis of the public health significance in meat and poultry products.

The Listeria program is not set in concrete; we will continue to consider adjustments as necessary for public health protection.

We were gratified that major industry groups such as the American Meat Institute promptly began to work with their membership to determine the extent of the inplant contamination problem and to develop guidelines, such as minimizing cross-contamination where cooked products are contaminated with bacteria from raw products during processing.

Raw poultry microbial control project. Since November 1987, FSIS has been conducting an onsite research project in Puerto Rico directed at reducing the spread of microbial contamination in the production of raw poultry. This project involves identifying points in the production process where contamination can be prevented or reduced, and testing alternative methods. Effectiveness is determined by comparing the results of before and after microbiological sampling.

One procedure, a hot water rinse in a special cabinet after scalding, looks promising. We are now considering possible replication of that trial in other plants -- a necessary step before it could be considered for mandatory application in all plants.

Some time ago, we contracted for a team of external scientific experts to advise us on the project. They are now examining results to date, and we hope to provide a report in early 1990.

Through the results of the raw poultry study, it is becoming increasingly apparent that the impact of changes in plant processing will be minimal unless contamination levels on incoming birds can be reduced. Last week, FSIS staff discussed with a British company the feasibility of testing the company's feed additive in the project. Some studies show that organic acids in the supplement appear to block salmonella colonization in the animal's intestinal tract and to confer resistance to recontamination.

Initiation of this experiment is on hold, pending final FDA approval. We expect to proceed with this and any other feasible approaches that promise possible reductions in bacterial loads.

Education. The first NAS report urged us to extend our educational efforts to more audiences, including health care workers, educators, USDA Extension agents, and food industry workers. The second NAS report on poultry inspection urged us to make our educational efforts more "systematic." We have been responsive to both sets of recommendations.

We are working steadily to improve coordination with the Extension Service. In the past, one of our major activities was to disseminate FSIS food safety publications and consumer alerts through the Extension system, which reaches millions of Americans. Now, we are working even more closely with the Extension Service on specific projects. For example, FSIS staff have been included in reviewing research proposals from the States for projects in risk communication. We will continue to strengthen our ties, for better coordination can vastly multiply our effectiveness in influencing behavior.

FSIS developed a video and training kit for institutional food service workers, "Food Safety is No Mystery," which has received professional recognition in food safety education circles and awards in public affairs circles. Inexpensively priced, more than 11,000 copies have been ordered by thousands of restaurants and restaurant chains, nursing homes, daycare centers, local health officials, and others.

Because many foodservice workers do not speak English as a primary language, we are now exploring the possibility of a Spanish version. In that regard, we are also pretesting a comic-book style food pamphlet directed at low-literacy audiences.

We are also in the midst of a broad education campaign directed at health professionals and high-risk consumers, who comprise at least 15 percent of the population.

Effective education can change behavior, and food handler behavior can prevent much foodborne illness. Recently, we released the report of an 18-month interdisciplinary project to apply a risk-based approach to food safety education. Our objective was to identify the home food handler behaviors that are most important in preventing foodborne illness, but least understood or practiced.

One significant conclusion of the report is that food safety educators should stress refrigeration of cooked food within 2 hours after serving in shallow, covered containers. Epidemiological information shows failure to carry out these steps has been a factor in many outbreaks, and microbiological experts agree on the importance of these steps. However, survey information shows about 67 percent of home food handlers would not hesitate to refrigerate cooked food in one large container or the cooking pot.

We are using the report to develop a new consumer publication and as an aid in planning future educational activities.

PUBLIC HEALTH RISKS RELATED TO CHEMICAL AGENTS

The public is concerned about chemical residues. So is the Food Safety and Inspection Service. Although the evidence indicates the health risk of residues in meat and poultry products is slight, we can never entirely rule out the possibility of a contamination incident that would pose significant health risks to the average American.

We have undertaken a number of initiatives in the recent past to improve our residue program. The National Residue Program includes a statistical, random-sampling monitoring program designed to assure, with 95 percent confidence, that a residue problem in 1 percent or more of the animal population, nationwide, will be detected.

This level of confidence is reasonable. Today's animal production methods mean that animals are generally raised under controlled conditions, with exposure to the same medications and feed, including exposure to the same risks of contamination.

FSIS has increased sampling for residues of sulfamethazine and chlorinated hydrocarbon pesticides. The Administration's budget request for FY 90 includes an additional $1.8 million dollars to increase residue sampling and testing.

The monitoring program is not the only way we detect residue violations. Field inspectors play a key role in noticing atypical situations that may lead to intensified surveillance sampling, and our colleagues in the Food and Drug Administration or other agencies may alert us to problems. In some cases, responsible companies with their own residue testing and control programs may alert us to violations. We are encouraged that progressive meat and poultry companies are willing to invest in preventive programs, and we will work to make this a trend.

Exploratory testing can also provide useful information. It may be undertaken when the scientific literature, inspection data, or other information suggests a possible new problem area.

Ten years ago, the General Accounting Office (GAO) published a report critical of the effectiveness of USDA and other agencies in preventing the marketing of meat and poultry containing "potentially harmful" residues.

The GAO identified 143 substances as likely to leave residues, noting that about 68 were known or suspected agents of cancer, birth defects, or mutations. In 1979, USDA tested for only 66 compounds, including only 46 of the 143 GAO believed would leave residues. The NAS committee found our arsenal of tests inadequate, in view of the magnitude of the problem.

Last year, the residue program tested for 112 compounds, and we are testing for 120 compounds this year. Another indicator of progress is volume. In 1980, the inspection program analyzed 200,000 analyses; only 65,000 were for residues. In FY 1988, FSIS analyzed more than 463,000 samples, of which almost 327,000 were for residues.

This dramatic increase was made possible largely by the advent of rapid testing. In 1980, the Swab Test on Premises (STOP) to detect antibiotic residues in cull dairy cows was just being implemented. Since then, we have implemented other rapid tests for antibiotics and sulfa in live animals. These tests can be used on the farm as well as in the plant.

We are continuing to develop new and better test methods. For example, we are evaluating a commercial ELISA test for chlorinated hydrocarbon pesticides such as chlordane and heptachlor.

We are also evaluating a cholinesterase test for organophosphate and carbamate pesticides -- accounting for many of the pesticides currently used in agricultural production. We are working with a company that has developed a multiresidue system for human drugs to develop a similar system for veterinary drug and pesticide residues. If this approach is successful, it would improve our laboratory efficiency and reduce laboratory testing costs.

We are also cooperating with other agencies such as the Department of Energy and the Environmental Protection Agency to develop ELISA test methods for veterinary drugs and pesticides. We need to focus on improved procedures for extracting residues from test samples to more effectively employ the rapid tests that have been and are being developed.

In the last few years, in response to the NAS recommendation for more risk assessment, we have established a systematic Compound Evaluation System to choose the compounds that will be included in the monitoring program. Working from a list of about 400 compounds that could possibly result in residues in animal tissue, we determine the potential for animal exposure and the human health significance. Compounds with the highest priority are those that are highly toxic and highly likely to be present.

The process of compound evaluation never ends, because the situation can change very much from year to year. Our 1990 budget request includes funding for risk assessments of 50 new compounds per year, up from 10 in the past.

In addition to recommending more tests, the NAS recommended the development of "new techniques such as automated laboratory methods for analysis and measurement, imaging techniques, and computer-assisted information transfer." FSIS agrees that such technology can improve efficiency in field and laboratory settings.

The Agency has two automated methods in place; one is an automated residue extraction system coupled to a rapid laboratory screening test. In two laboratories, we are developing automated methods, to use commercially available robotic systems. Research is also underway on automating analytical methods for antibiotics and ivermectin; the latter is a very labor-intensive regulatory method.

An exciting technology ripe for development is the coupling of computer-assisted systems to rapid-inplant tests. We are evaluating such a system for use with the Sulfa-on-Site (SOS) test, and we plan to explore the approach in field studies.

By combining a personal computer with a small vidicon (television) camera, a non-scanning fluorescence spectrometer, and an image capture board, SOS plates could be read more precisely, and automatically, with minimal inspector intervention. The system would also document its own results, freeing the inspector from data entry and evaluation. The entire instrument is small enough to fit under an airline seat and rugged enough to be carried from site to site.

The system, with modifications, also has potential application to other onsite tests; for example, aflatoxin screening, multivariant analysis of simple chromatography for pesticides, other veterinary drug classes and environmental contaminants, analysis of gel immunodiffusion plates, microbiological agar plate counting, and ELISA microtiter tests.

Testing sensitivity, accuracy, reproducibility of results, and improved data quality control and management in both residue and microbiological testing potentially could be enhanced by using this system. For example, test results could be transmitted electronically with a minimum number of keystrokes, reducing the need for inspectors to fill out forms by hand.

Despite our technological progress, we must remember that technology is a management tool and not a solution. A residue program that meets the spirit of the NAS report is one in which tests and new technology are continuously incorporated as they prove themselves useful in preventing residues.

This philosophy is visible in the sulfa initiative. FSIS used the rapid Sulfa-On-Site (SOS) test in a carefully considered, massive, year-long surveillance program for sulfa in swine that succeeded in greatly reducing the levels of violations. Sulfamethazine violations from the 1988 monitoring program declined to 1.42 percent -- the lowest ever. Nonetheless, we do not regard this or any other residue problem as "solved".

The NAS report observed that cooperative programs appear to be successful in minimizing residue problems before they reach the plant. FSIS believes that such programs are consistent with a risk-based, preventive residue program. We are preparing a proposal to encourage

more plants and their suppliers to institute such residue control programs. We recognize the need to assure that objective scientific data is used as the basis for verifying the effectiveness of these programs.

The last item I would like to mention in the area of chemical residues is our Residue Violation Information System (RVIS) This automated library of data about nationwide violations enhances USDA's ability to prevent residue violations. It also facilitates interagency cooperation -- a characteristic of the optimal program described by the National Academy of Sciences. For example, FDA personnel can key into a computer to find the information they need to follow up on a possible violation. RVIS now contains residue information dating to October 1986.

INSPECTION MODERNIZATION

To this point, I have addressed some of the progress the Agency has made in strengthening our scientific ability to deal with two public health risk areas associated with meat and poultry. I would now like to describe how we have modified the program as a whole, including basic inspection, to move toward "a risk-based allocation of resources, supported by modern technology and a systematic evaluation of the program."

Some have implied that we should make no changes to the program at all until the scientific basis is complete. With all due respect, that is a little like saying no one should research human genetic diseases until the map of the human genome is complete.

Modernization toward the optimal inspection program has proceeded on the principle that FSIS needed to reverse the trend that placed more and more responsibility for food safety on inspection personnel. A fundamental concept of modernization is to establish clear responsibility in the regulated industry for the safety of their products, with effective FSIS oversight.

Another important principle underlying modernization is that traditional inspection procedures should be streamlined to enhance productivity and allow the redirection of scarce resources to high-priority public health objectives. We have made progress in both areas over the past decade, and we are ready for the next challenge to incorporate more effective procedures into day-to-day workings of the Agency.

I want to make it very clear that none of these changes has eliminated carass-by-carcass inspection at slaughter, which is required by the federal inspection laws.

The past ten years. Over the past decade, we have made many improvements to the program and inspection procedures. It can be seen that each improvement satisfied the basic principles of our framework for modernization. Also, implementation of each new inspection procedure was preceded by careful evaluation, field tests and pilot tests, documentation, and public comment through the rulemaking process.

We implemented voluntary Total Quality Control (TQC) Inspection for processing in 1980.

TQC inspection placed more emphasis on responsible segments of industry to assure and document their compliance, and included more objective USDA oversight techniques. In its 1985 report, the NAS committee noted that TQC processing inspection is "not likely to reduce public health protection."

Next, FSIS added a QC inspection component to some slaughter inspection procedures. Streamlined Inspection Systems (SIS) for Poultry have been very effective. Such systems focus plant management on disease detection and set clear finished product standards for plants to follow, by which USDA can monitor their compliance.

In its 1985 report, the NAS committee also stated that new slaughter inspection procedures implemented by the time of their review "are not likely to diminish protection of the public health." At the same time, the committee strongly recommended incorporating formal risk assessment and the HACCP approach into all aspects of inspection.

The newest proposed system, Cattle-SIS, has been in the news recently. Although the development of this proposal began prior to the NAS report, all available in-house resources in the disciplines suggested by NAS were tapped for advice and critiques. The proposal was published in November 1988, and the comment period has concluded.

FSIS has decided to convene a group of outside experts to assess the functioning of Cattle-SIS procedures in pilot demonstration plants, and to compare the results in these plants to those in plants operating under traditional inspection procedures.

In its 1985 report, the NAS committee recommended an expert standing committee of outside experts to review certain critical proposals. FSIS determined that the specific recommendation could not be implemented. A committee with the level of expertise required, in the variety of disciplines needed for FSIS programs, would be very large and expensive to maintain on a permanent basis. Instead, FSIS opted to convene panels of experts, assembled on a case-by-case basis.

The National Advisory Committee on Microbiological Criteria for Food shows that this approach can be effective. In a relatively short amount of time, the Committee has accomplished much in terms of framing the issues in a way that allows scientific and practical responses to be developed. The 24 members of the Committee have met eight times during the past 16 months.

The Committee is now divided into two working groups. The Seafood Working Group is preparing recommendations on microbiological criteria for cooked ready-to-eat shrimp and cooked ready-to-eat crabmeat. The Meat and Poultry Group is drafting recommendations on prepared refrigerated products containing cooked, uncured meat and poultry. An ad hoc group of members has been drafting general principles for the application of the HACCP approach in food safety programs.

Thus far, the Committee has transmitted recommendations for (1) the formation of an interagency task force to consider a uniform standardized label statement and logo system for all packaged foods that pose a safety hazard when subjected to temperature abuse; and (2) an enhanced research support infrastructure. At its most recent meeting, the Committee approved for transmittal rec mmendations for (3) education and training throughout the food chain. The Committee's recommendations are transmitted to the Secretaries of Agriculture and Health and Human Services for consideration. This approach has been so useful we are exploring the idea of an interagency committee on chemical residues.

Consistent with the spirit of the NAS recommendation, we are now instituting an expert review of Cattle-SIS. Five experts in public health, veterinary medicine and meat science will be asked to gather information comparing Cattle-SIS and traditional inspection. This will enable the Agency to comprehensively evaluate Cattle-SIS alternatives. The results of their review and public comments will be considered before any decisionmaking proceeds.

PBIS. The Performance-Based Inspection System (PBIS) incorporates all that we have learned from Total Quality Control Inspection, the Intensified Regulatory Enforcement Program, and the Inspection System Work Plan (which was developed to apply the concept of a standardized inspection plan to non-TQC processing plants). It will provide the Agency with more efficient and effective documentation for inspection management and enforcement.

PBIS maintains a cumulative record of plant compliance histories, based on results of inplant inspection, and schedules inspection work, based on risk-related frequencies. PBIS has the capability of scheduling and tracking results from 443 different inspection tasks that may be appropriate, depending on the plant. The majority of those tasks involve hands-on inspection, and the balance focuses on monitoring plant control systems.

It concerns us that there is a perception in some quarters that inspectors have become robots under PBIS. I want to emphatically state here that our inspection system preserves the fullest independent judgment by inspectors.

The General Accounting Office is now reviewing the PBIS system, and we look forward to reviewing their findings.

The USDA Office of Information Resource Management has been asked to do a selective review of the system, from which we also hope to gain useful information. We know the current PBIS system is not perfect, and we intend to keep refining it. Part of our problem is that we have not been able to afford the system we need to make maximum use of inspection data to improve public protection. Our 1990 budget request includes funding for improving computer systems.

HACCP. FSIS has been working to incorporate the HACCP approach into the program for several years. Staff in slaughter inspection, processing inspection, and other program areas have become familiar with HACCP concepts, which are not inconsistent with much of what we already do. In the past year, senior management staff received some extensive training from HACCP experts.

We are now developing an action plan for implementing HACCP in meat and poultry inspection. This will include an examination of the process used by the National Marine Fisheries Service to establish HACCP in their model seafood surveillance program. We believe HACCP may have equal application to meat and poultry inspection.

We are also seeking to educate the inspection force. Since the introduction of TQC in 1980, 1,500 inspectors and supervisors have received training in quality control and critical control point concepts. We are planning to include a specific HACCP curriculum component in the Agency's training for all veterinarians and food inspectors. In addition, we constantly encourage companies to develop their own HACCP systems approach to process control.

Data Systems. Computerization of data is a reasonable objective for any government agency in the waning days of the 20th Century. The U.S. Customs Service, FDA, and many other regulatory agencies have made progress in incorporating data automation as a management tool.

Computerization of data is not only useful but critical for a public health agency. The 1985 NAS report found FSIS deficient in this area, noting that an optimal inspection system would have a "rapid, timely, and flexible system" for acquiring, transferring, and analyzing data. Today, we have greatly strengthened our computer capabilities and our workforce's ability to use that tool to protect public health.

To date, FSIS has installed and actively uses 1,000 small computers. Microcomputers are used for recording plant compliance, analyzing inspector reports, scheduling sampling,
and triggering regulatory actions when sample results show noncompliance. Small computers and terminals are linked over short and long distances to integrate systems. For example, plant location and inspection history can be cross-referenced with such information as label ingredient statements.

We are reaching the point at which we will be able to use these databases to support legal action based on chronic noncompliance, quickly redirect inspectors to possible urgent health hazards, assess the overall performance of the industry on specific processes, and pinpoint areas needing more emphasis.

Several data systems are in place and are continually being improved upon. RVIS has already been mentioned. Another important system is CORE, the Common Online Reference for Establishments. CORE now contains basic information about the plants and operations under

inspection. In the future, it will probably act as a link among several Agency systems.

Other systems include:

MARCIS - Microbiological and Residue Computer Information System;

ADRS - Animal Disease Reporting System;

REIS - Review and Evaluation Information System;

ICS - Inspection Coverage System. In the field-testing stage, this system or a modification will enable the complex scheduling task to be automated. Now, the effective scheduling of inspectors, including coverage of vacant positions or vacationing or ill inspectors, is done manually.

A decade ago, perhaps only ten employees had the computer access, technical skills, and understanding to use a computer with confidence. Few can recall the work and rework necessary only 5 years ago to produce a simple typewritten document or a roster of work assignments in alphabetical order. FSIS has made a concerted effort to draw employees at all levels into the computer age, to replace a pad and pencil mindset with a broad understanding of Information Resource Management. This process will continue indefinitely.

Human resources. People are the core of the Agency. FSIS is a labor-intensive agency employing 9,700, the vast majority field inspectors.

The NAS report suggested improvements in the area of training and scientific expertise. We have made strides in both.

Through a program based in Athens, Georgia, we are drawing more highly skilled scientists into our program. Through a cooperative program with Johns Hopkins University, we are broadening the public health expertise of other employees.

The scope and depth of training has also been broadened for the basic inspector. We are proud of the new Donald L. Houston Center at Texas A&M University. I believe it is the legacy Dr. Houston would have wished.

In preparation for the integration of our training program with Texas A&M, the entire training curriculum was exhaustively reviewed, updated, and expanded, by experts inside and outside the Agency. Transferring the Training Center to the University has allowed us to dramatically expand the scientific and technical education presented to our inspectors and veterinarians.

The impact of this curriculum development on the training program is evident at all levels.

The technical content of the curriculum for newly hired inspectors has increased by 50 percent; for basic processing inspection, 100 percent; and for newly hired veterinarians, 100 percent. Today, approximately 60 faculty members from 13 departments and 5 colleges deliver more than 45 percent of the formal classroom training provided to Agency personnel.

In recent years, we have added to the curriculum for veterinarians such courses as histopathology, parasitology, food microbiology and pathogenic microbiology, computer applications, and statistics. We have also expanded the content of instruction in gross pathology, food animal diseases, biological residues, and submission of laboratory samples.

The recently developed curriculum for the food technologist includes thorough training in food microbiology, meat chemistry, computer applications and statistics, the nutritional value of meat, and quality control concepts.

For 1990, we have received a $943,000 increase to inaugurate a new supervisory training program and to train the 100 new food technologists we hope to add to the program by the end of Fiscal Year 1990. Many of those positions we hope will be filled by current employees.

As of June 30, 168 food technologists were employed in field positions (in plants or in regional, area, or circuit offices), 60 percent of them former food inspectors and 40 percent new hires with food science training. Of the current inspector workforce, 153 are qualified as food technologists, and 102 have 15 to 19 credit hours toward the required 20 specialized hours.

This concludes my discussion of the Service's scientific and technological capability. I hope that it shows, in sufficient detail, our concerted and directed movement toward the public health inspection program recommended by the National Academy in its review.

RESEARCH NEEDS

I would like to turn now to the issue of food safety research. I am aware that the Agricultural Research Service now provides $13.0 million for such research in support of FSIS and the an additional $4.7 million is now being considered by the Congress for the Fiscal Year 1990 budget.

Our research needs fall into two basic areas — microbiological and chemical risk reduction. Through an annual agreement, the Agricultural Research Service has completed many research projects for FSIS needs over the years. Last year, other ARS funds were redirected to food safety projects.

Risk assessment is becoming increasingly important to determine priorities for research and regulation. This is the process by which the qualitative or quantitative characterizations are made of the potential health effects of particular substances on individuals or populations. Risk assessment includes:

-identification of potential hazards;
-information on infective or toxic doses;
-assessment of the number of people likely to be exposed and
to what amount;
-the risk characterization of the economic and social impacts.

Microbial risk reduction. We need to improve our understanding of the sources and modes of transmission of foodborne and waterborne pathogens in order to develop and implement effective control measures. This is particularly true for bacterial species such as salmonella and Campylobacter, but it is also true for parasites and viruses.

We also need to learn more about the resistance of pathogens to heat, freezing, pH extremes, water activity, oxygen, and other factors that influence microbial survival and thus food safety. Established verities, such as the ability of refrigeration to halt growth of all pathogens, have been overturned in recent years.

The need for innovative, rapid, automated, and cost-effective detection methods has already been mentioned. Gene or DNA probes, monoclonal antibodies and other biosensors, and ultrasound are the newest areas of detection methodology that can be more fully utilized to produce useful methods.

Some bacteria produce toxins, and some toxins are heat-resistant. Thus, it is important to more fully understand the conditions under which bacteria produce harmful toxins, their mode of action, and ways to prevent or eliminate the toxins.

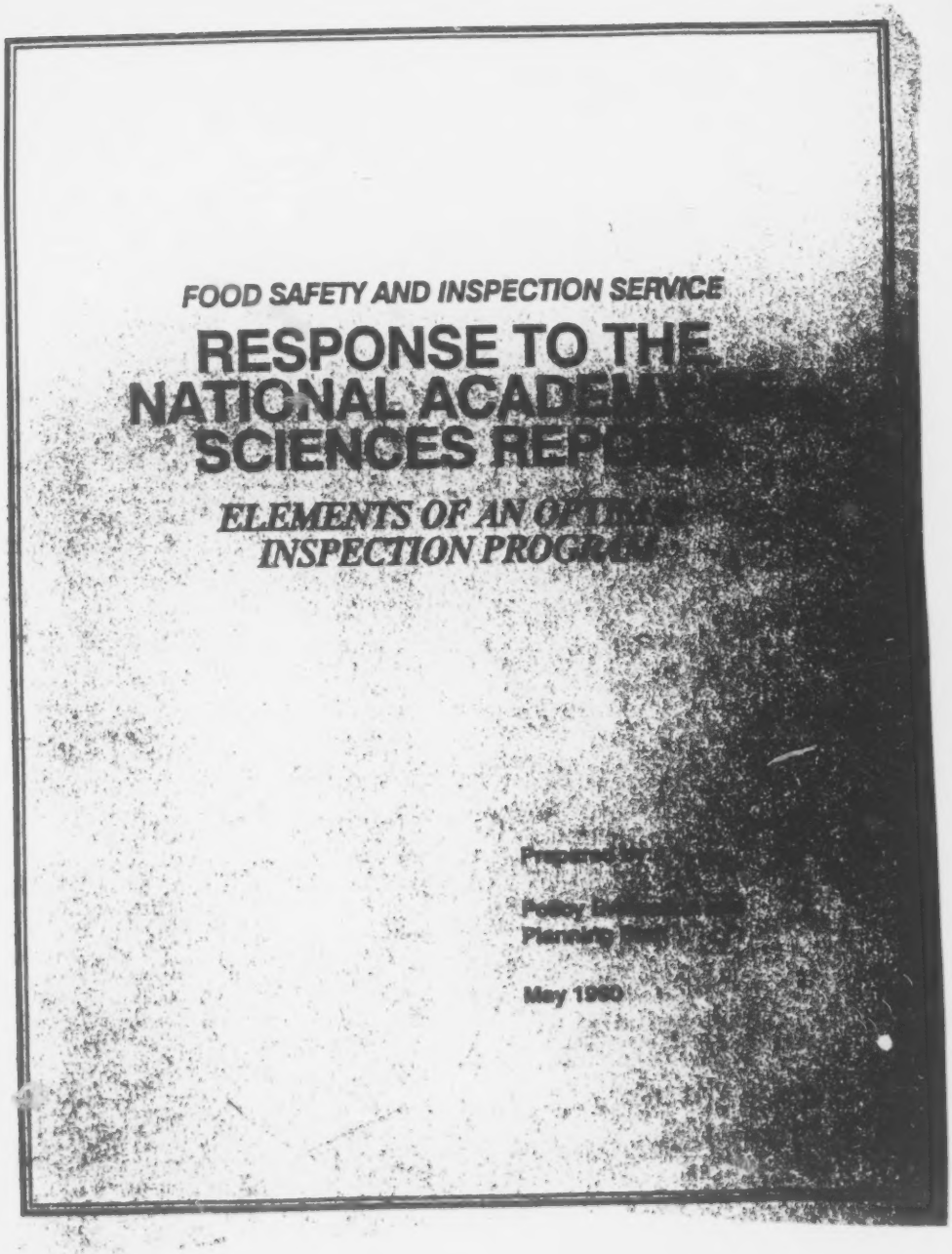
We need to define parameters for both the composition and treatment of food to assure its continued safety under a variety of conditions of handling and storage. This is particularly true for new products in new packaging. We also need to learn more about the risks of fresh and marine food products, and the cost of foodborne illness.

We must learn more in all these areas in order to assess and control the risks associated with microbial contamination in our food and water.

Chemical risk reduction. We need to identify and accurately quantify the long-term chronic effects of potential chemical hazards, in order to define negligible risk. We also must more accurately access actual exposure of humans to specific chemicals, using reliable residue screening tests.

More analytical methods, particularly multiresidue screening methods, are needed. We need to delineate the movement through the food chain of animal drugs, food, and drug additives, pesticides, sanitizers and environmental contaminants. We must develop techniques for control by pesticide users, including integrated pest management. And finally, we need more research in the area of risk communication.

This concludes my testimony, Mr. Chairman.


FOOD SAFETY AND INSPECTION SERVICE
RESPONSE TO THE
NATIONAL ACADE
SCIENCES REP
ELEMENTS OF AN OP
INSPECTION PROGR
Prepared by
Policy
Planning
May 1980

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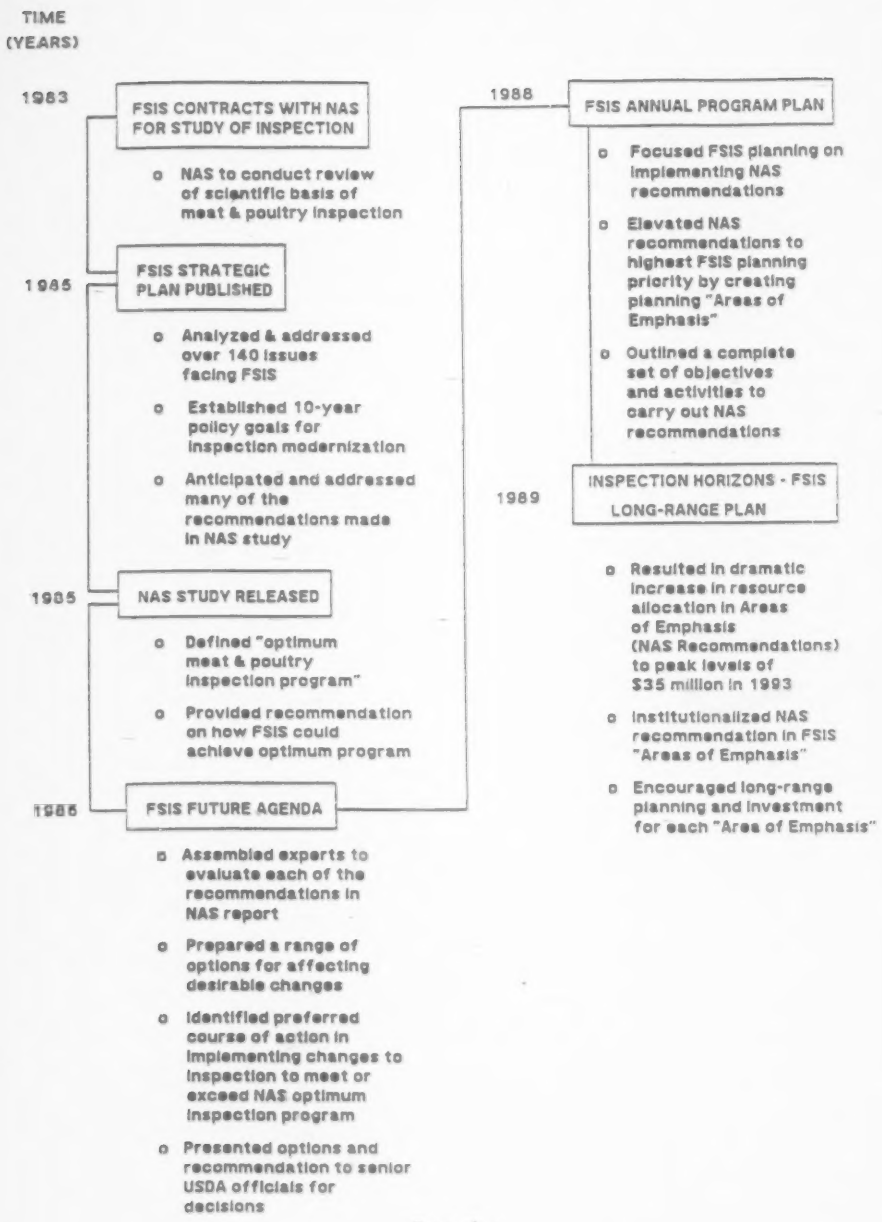
CHRONOLOGY OF MAJOR EVENTS


TIME
(YEARS)
1983
FSIS CONTRACTS WITH NAS FOR STUDY OF INSPECTION
o NAS to conduct review of scientific basis of meat & poultry inspection
1985
FSIS STRATEGIC PLAN PUBLISHED
o Analyzed & addressed over 140 issues facing FSIS
o Established 10-year policy goals for inspection modernization
o Anticipated and addressed many of the recommendations made in NAS study
1985
NAS STUDY RELEASED
o Defined "optimum meat & poultry inspection program"
o Provided recommendation on how FSIS could achieve optimum program
1986
FSIS FUTURE AGENDA
o Assembled experts to evaluate each of the recommendations in NAS report
o Prepared a range of options for affecting desirable changes
o Identified preferred course of action in implementing changes to inspection to meet or exceed NAS optimum inspection program
o Presented options and recommendation to senior USDA officials for decisions
1988
FSIS ANNUAL PROGRAM PLAN
o Focused FSIS planning on implementing NAS recommendations
o Elevated NAS recommendations to highest FSIS planning priority by creating planning "Areas of Emphasis"
o Outlined a complete set of objectives and activities to carry out NAS recommendations
1989
INSPECTION HORIZONS - FSIS LONG-RANGE PLAN
o Resulted in dramatic increase in resource allocation in Areas of Emphasis (NAS Recommendations) to peak levels of $35 million in 1993
o Institutionalized NAS recommendation in FSIS "Areas of Emphasis"
o Encouraged long-range planning and investment for each "Area of Emphasis"

FOOD SAFETY AND INSPECTION SERVICE

RESPONSE TO THE NATIONAL ACADEMY OF SCIENCES REPORT

ELEMENTS OF AN OPTIMAL INSPECTION PROGRAM

BACKGROUND

1. Origin of NAS Report

In order to maintain consumer confidence in the Nation's meat and poultry supply during a period in which many changes had taken place in meat and poultry inspection, the Food Safety and Inspection Service (FSIS), in November 1983, contracted with the National Academy of Sciences (NAS) to review, from a scientific point of view, the ability of the inspection program to maintain the traditional level of consumer protection.

2. NAS Report

The NAS report, *Meat and Poultry Inspection: The Scientific Basis of the Nation's Program*, which was published in July 1985, found that the inspection program, even with its changes, was maintaining its traditional standard of consumer protection. It made recommendations for ensuring that the program would be able to maintain that standard and, perhaps, even improve its performance, in a world that was and is becoming more technologically complex.

The NAS report postulated an "optimal" model of meat and poultry inspection and compared the FSIS program of that time with the model. It found that the current FSIS program measured up well to the model. This result was anticipated because FSIS had started its program of modernization about eight years earlier and had made considerable progress during that time in accommodating new detection and production technologies. Where the current program deviated from the optimal model, NAS made recommendations for improvements. These recommendations took the form of "elements" of an optimal program. There were 17 of these "elements." FSIS was already addressing many of them through its modernization efforts. In cases where "elements" of the model were being insufficiently addressed or unattended entirely, FSIS immediately set in motion planning activities that would address the deficiencies.

3. FSIS Response

As part of its long-range planning process, in 1986 FSIS reviewed each NAS recommendation, evaluated its relevance to the Agency's responsibilities and capabilities, and presented a range of options for effecting desirable changes. The scope of the review is reflected in the *FSIS Future Agenda Response to the NAS Recommendations*. Experts from within and without the Agency endeavored to provide every possible

course of action available to FSIS in implementing an approach to inspection that would meet or exceed the characteristics of the NAS optimal program. In each case a preferred course of action was identified and recommended with the understanding that the final decisions would rest with senior officials in the Department of Agriculture. Those decisions were made by the Secretary of Agriculture and were incorporated in the final published version of the *FSIS Future Agenda*. The decisions made by the Secretary were translated into FSIS planning objectives and activities, many of which are ongoing today.

4. FSIS Review Process

After the NAS report was published, FSIS organized a series of committees to respond to the report's recommendations. These committees and their assignments corresponded to the major recommendations in the report. The eight committees were as follows:

- Animal Identification and Traceback
- Microbiological Contamination
- Residue Control
- Disease Control
- Data Systems
- Methods Development Agenda
- Agency Technical Capability
- Public Education

Each committee had members from both inside and outside FSIS because so many of the regulatory problems discussed by the NAS report were beyond the jurisdiction of FSIS. (A detailed list of committee memberships is contained in the attachment at the end of each report contained in the *FSIS Future Agenda*.)

Each committee evaluated a wide range of options in making its recommendations. The NAS report and the activity associated with it provided the Agency with the opportunity to step back and look at its program through the eyes of others. This activity fortunately coincided with the Agency's new long-range planning activity. Thus, after decisions were made with respect to the general activities suggested in the NAS report, the Agency was prepared, through its planning mechanism, to elaborate on the implementation requirements for these activities and to establish responsibilities and schedules for their implementation. These activities and schedules were produced in detail and appeared in the FSIS Annual Program Plans of 1987 and 1988 and later in the Agency's 1989 long-range plan, "Inspection Horizons, FSIS Strategy for the 1990s."

FOOD SAFETY AND INSPECTION SERVICE

RESPONSE TO THE NATIONAL ACADEMY OF SCIENCES REPORT

ELEMENTS OF AN OPTIMAL INSPECTION PROGRAM

The following pages list, in sequence, each of the 17 elements of the NAS optimal program. Each element is then followed by a discussion of what the immediate FSIS response was and the current situation.

1. ANIMAL IDENTIFICATION AND TRACEBACK

NAS Recommendation

The NAS recommended that an animal identification system be established so that diseased or contaminated animals could be traced to their source, the farmers' share of responsibility for contamination could be clearly established, and epidemiological studies of specific disease outbreaks could be facilitated.

FSIS Response

FSIS began to implement this recommendation by promulgating a regulation that requires slaughter plants to maintain records on the ownership of all swine that have moved in interstate commerce prior to slaughter. The Agency is planning to evaluate this system and, if appropriate, expand it to other animals.

Recent Events

In October 1988, the Animal and Plant Health Inspection Service (APHIS) and FSIS jointly published a final rule requiring that all swine in interstate commerce, except farrow-to-finish swine, be identified and records concerning the swine identification be maintained. The limited exemption for farrow-to-finish requires that they be raised on the premises where they were born, shipped to slaughter as a group, not commingled with other animals during shipment, and slaughtered together as a group. Packers must maintain records only on those animals which were selected for residue testing at the time of inspection. APHIS recently updated the rule to clarify the point at which identification must occur. The rule is based on existing authorities of APHIS and FSIS.

On March 2, 1990, a final rule was published requiring producers and subsequent young calf handlers, who wish to certify that their animals are free from violative drug residues, to use standardized language on their certificates. The program is designed to provide incentives to industry to control drug residues in "bob veal" calves, which are calves up to three weeks of age or weighing 150 pounds or less. Each certified calf received for slaughter must be identified by a back tag, ear tag or other securely attached identifica-

tion which displays a number which must be recorded on all certifications. All individuals having custody of the calf prior to slaughter must make certification. This includes the producer, sale barn operators, and truckers. The chain of custody permits traceback of a certified calf to the producer if the animal is found to have violative levels of drug residues. Calves slaughtered under the voluntary program are tested less intensively than uncertified animals, which serves as an incentive for packers and producers to encourage and use voluntary certification.

2. MAXIMUM USE OF PLANT PERSONNEL TO MAINTAIN CRITICAL CONTROL POINTS (CCPs)

NAS Recommendation

The NAS recommended that maximum use of plant personnel is needed in process-by-process and day-to-day monitoring of critical control points, with FSIS oversight to ensure compliance.

FSIS Response

FSIS has implemented in most processing plants a concept of quality control that relies on plant personnel to perform process and product monitoring. This was done through the promulgation of Meat and Poultry Regulations 318.4, 381.145, 318.300, 318.309, 381.308, and 381.309. Process and product monitoring using Critical Control Points is done through plant-generated Partial Quality Control (PQC) programs and Total Quality Control (TQC) systems. FSIS evaluates all plants for compliance with regulations through its Performance-Based Inspection System (PBIS). PBIS has been designed to assign in a randomly sequenced order inspection tasks of predetermined frequencies to evaluate plant performance.

Recent Events

FSIS has elevated Hazard Analysis and Critical Control Point (HACCP) principles and education to a top planning priority by making it an "Area of Emphasis" in its current long-range plan. FSIS Areas of Emphasis are direct derivatives of the original NAS recommendations and receive first priority for attention and new funding within the Agency. The focus of HACCP activity at present is to educate the inspection workforce, the public, and the industry regarding HACCP principles and the intent of FSIS to implement HACCP. Ideas and suggestions for a successful implementation are being solicited from these groups. The Agency launched a two-year study in January 1990 to determine the process for implementation. Implementation over a period of several years will follow this study. The use of HACCP will better protect public health and promote consumer confidence in the safety of meat and poultry products by enabling establishments to:

- Identify hazards in their operations.
- Establish CCPs to monitor those hazards.
- Establish limits for each CCP.
- Develop procedures to monitor CCPs.
- Initiate appropriate corrective actions when problems occur.
- Document monitoring and corrective action procedures, such as testing at CCPs, to verify that the HACCP system is working correctly.

Inspectors will continue to verify plant process effectiveness by daily monitoring, conducting unannounced inspections, and collecting product samples for testing. With a HACCP public protection system in place, FSIS will be able to verify, for both slaughter and processing activities, that each company is controlling its processes. If a company is not doing so, a range of enforcement actions could be taken, in keeping with current Agency enforcement authority.

In addition, slaughter inspection is being upgraded to make more efficient use of plant personnel. The Agency's streamlined inspection system for all species, or SIS, incorporates several of the recommendations made by the NAS. Many of the concepts and principles underlying SIS are the same as those found in HACCP. These include identifying critical control points for each process or procedure, using random sampling to verify performance, and increasing the use of plant personnel to perform tasks for which the plant should be responsible. Under SIS, plants assume the responsibility for dressing defects, trimmable conditions, and other nonconformities that are easily identified and do not require the special training and experience of an inspector to correct. FSIS still assumes full responsibility for assuring public health and safety, but plants assume a larger responsibility for producing products that are free of defects, such as hair and bruises. Plants are also responsible for taking corrective action, with FSIS oversight.

3. AGENCY TECHNICAL CAPABILITY

NAS Recommendation

The NAS recommended that FSIS increase its access to technical expertise by the use of advisory committees, continuing education and training for its staff, and more interagency liaison with relevant scientific and animal health groups.

FSIS Response

As outlined in its Strategic Plan, FSIS was planning to improve its accessibility to technical expertise by using as a guideline the realities of the marketplace (i.e., who can the Agency successfully recruit and keep) and the cost of training. After analyzing its needs for more expertise, the constraints presented by the marketplace, and the cost

of training, FSIS decided to recruit whenever possible food technologists who are already trained in their disciplines (food science, food technology, and public health) and to use its training resources to educate Agency personnel in applied meat and poultry inspection technologies. For specialists that the Agency only uses from time to time, or for which it is at a comparative disadvantage in recruiting, FSIS would utilize advisory or contractual modes. The Agency also planned to use a Basic Ordering Agreement, a form of contract that allows the flexible use of scientific personnel and other expertise, to obtain services as needed. FSIS also planned to investigate the appropriateness and desirability of using more advisory groups.

Recent Events

FSIS has embarked on a ten-year program to increase the number of food technologists in complex processing inspection assignments in order to enhance its technical capability. To date, the Agency has hired and trained over 219 food technologists, 67 of whom have been converted from the Agency's inspector ranks. FSIS has also embarked on a program of training FSIS personnel as pathologists, a technical discipline for which it has experienced difficulty in recruiting.

In order to keep abreast of developments in biotechnology, the Agency is planning to train two employees on a university campus during 1990-1991. Also, a basic introduction to biotechnology has been added to the curriculum in the FSIS inspection training program at Texas A&M University.

In addition, FSIS has convened the National Advisory Committee on Microbiological Criteria for Foods as a direct response to the NAS recommendations.

More on what FSIS has done to respond to this NAS recommendation is contained in the discussions on interagency advisory and liaison committees, optimal elements #s 15 and 16, respectively.

4. RISK-BASED INSPECTION

NAS Recommendation

The NAS recommended an inspection system with **different levels of intensity**, reflecting the degree of public health risk at various stages in the process, the reliability of the monitoring system, the compliance history of the slaughterhouse or processing plant, and the special needs of the intended consumer (e.g., military personnel and schoolchildren).

FSIS Response

FSIS has implemented PBIS, which schedules inspection tasks at frequencies and intensities commensurate with public health risk, accumulates inspector findings in an

FSIS database, and establishes a corrective-action, progressive enforcement system based on the compliance history of the inspected establishment. Frequency and intensity of inspection under this system have been determined through the development of FSIS regulations, directives, and policies. The ability to constantly monitor and update plant performance in the FSIS database, will enable the Agency to make corrective actions based on the data and achieve the primary goals of the NAS recommendation.

Recent Events

FSIS has developed and implemented a streamlined inspection system for poultry. The Agency has developed, tested, and proposed implementing a somewhat comparable streamlined inspection system for cattle--much larger animals than poultry and subject to several different inspection procedures. (See optimal element #2 above, Maximum Use of Plant Personnel to Maintain Critical Control Points). Like the HACCP system, this new system of inspection uses the concepts of risk assessment and risk management by placing valuable inspection resources where they can produce the maximum advantage in assuring safe and wholesome product. Under SIS procedures, plants assume greater responsibility for process control, allowing inspectors more time for oversight and inspecting carcasses and other animal parts for disease. An integral part of fully mature streamlined inspection is the maintenance of a documented history on a plant's performance. Such information will help the Agency make the appropriate response to changing plant conditions.

5. DISEASE MONITORING

NAS Recommendation

The NAS recommended that FSIS develop a list of the diseases that can be identified at each step in the inspection procedure. This list should be used to distinguish steps useful solely for detecting aesthetically objectionable conditions from those with health or safety consequences.

FSIS Response

Since the time of the NAS recommendation, FSIS has been working to develop the list of diseases called for by the NAS. This project has been underway since FY 1986 and is currently funded through FY 1993.

Recent Events

At present, the project is focused on developing an inclusive disease listing for swine. In order to accomplish this, Agency pathologists have been collecting data on the causes of condemnation of the 85 million swine that are slaughtered annually. When sufficient data have been collected to correlate condemnations with specific diseases, this infor-

mation will in turn be compared and correlated with APHIS data on farm diseases. The model produced by the swine project will then be replicated for other species. More information on this activity is contained in the following discussion on disease control.

In order to improve the effectiveness of disease monitoring, the Agency has made a commitment to upgrade and enhance the Animal Disease Reporting System (ADRS). ADRS is a computerized system for maintaining data on livestock and poultry slaughtered under inspection, inspection findings, and the disposition of inspected carcasses. From the data stored in the system, summary information can be retrieved for use by staffs within FSIS and by other agencies for various reporting purposes, including reports to Congress. Among the many enhancements planned for the system are the establishment of a systematic data quality assurance program, improvements in data retrieval and access, and expanded data analysis and reporting functions.

6. DISEASE CONTROL

NAS Recommendation

The NAS recommended that FSIS undertake a definitive diagnosis activity that will help the Agency focus on the prevention of diseases throughout the animal production chain.

FSIS Response

Beginning in 1985, FSIS was helping to support an activity being conducted by the Extension Service with the participation of three universities. This activity explored what types of definitive diagnostic data can be generated in plants where inspection is taking place, the mechanism for recording and feeding back such diagnostic data to the feedlot and veterinarians, and whether the improved information will, in fact, improve herd health management.

If results from the Extension Service study indicate that a definitive diagnostic activity appears to be effective, FSIS is receptive to using laboratory capability it can spare to start a pilot program of its own to explore further the feasibility of integrating a definitive diagnostic activity into its inspection systems. By the time the Agency is ready to initiate a pilot program, it is likely that some of the complementary mechanisms, such as animal identification systems and improved data automation, will be available to facilitate program implementation.

The success of this pilot program will determine whether new funds, or funds from less productive inspection procedures, should be used for the increased laboratory capability that would be necessary to support a greatly expanded definitive diagnostic activity. In further support of this activity, FSIS elevated the issue of disease control to a top planning priority by making it an "Area of Emphasis" in its FY 1988 Annual

Program Plan. Two major objectives in support of the disease control Area of Emphasis were established:

1. Improve ability to do specific disease diagnosis at official establishments.

2. Develop procedures to gather and use information obtained from disease diagnoses. Develop a program for statistical sampling of food animals to identify the principal causes of retention, trimming, and condemnation, and work with other agencies to provide this information to animal producers so that overall animal health can be improved.

Both of these objectives are presently being carried out by Agency pathologists (see #5 above) and are funded through FY 1993. Specific activities in support of these objectives are listed below:

1. Develop and operate a statistical sampling program to identify the principal causes of retention, trimming, and condemnation.

2. Develop and operate a computerized system for relating the identified causes of condemnation to species, sex, age, season, geographic origin, transportation, and related factors.

3. Develop and operate a computerized program for early identification of an usually high or low condemnation rate by Region, Area, Circuit, and abattoir.

Recent Events

FSIS has made a major commitment of resources in satisfying the NAS recommendations. This commitment is reflected in the Agency's 1989 long-range plan where activities in support of definitive disease diagnosis are scheduled through FY 1993. A further indication of the importance FSIS attaches to the issue of disease monitoring and control is reflected in the recent decision to upgrade and enhance the ADRS, a database specifically designed to record nationwide condemnations.

7. RAPID TESTS

NAS Recommendation

The NAS concluded that the analytical tools and testing capacity of FSIS are inadequate and that the Agency should continue to make revisions in its testing procedures to accommodate changing needs. In particular, it noted the continued need for rapid, inexpensive screening tests to detect a broad array of hazardous chemical compounds.

FSIS Response

FSIS agreed that it must have the capacity to undertake methods development research, and subsequently asked Congress for support to build the capacity to develop more durable, easily performed rapid screening tests for laboratory, in-plant, and on-farm use. FSIS continues to develop and introduce rapid tests.

In 1988, the Agency began use of the Sulfa-on-Site (SOS) test which it developed and provided to industry, veterinary organizations, and extension specialists to help producers identify and correct sulfa problems. There is evidence that the use of this test has decreased the incidence of sulfa residues in swine.

A problem of residues in young "bob" veal calves that had been medicated shortly before slaughter was reduced from a 7 percent violative rate to 2 percent when the Agency, using the Calf Antibiotic and Sulfa Test (CAST) which it developed, implemented an in-plant testing certification program.

The Swab Test on Premises (STOP) program in 1988 represented a major contribution to reducing the problem of antibiotic residues in cull cows.

Also in 1988, FSIS pilot tested a "card" test for Chloramphenicol residues in two plants. Chloramphenicol is an antibiotic banned for use in food animals because it can cause a fatal type of anemia in humans. The test is performed in-plant by inspectors on calves already condemned or CAST positive. The Food and Drug Administration (FDA) and FSIS must determine what legal actions will be taken if the Agency begins condemning calves due to the presence of residues of the illegal drug Chloramphenicol.

Recent Events

Rapid tests for drug and chemical residues are being developed not only for in-plant inspection procedures but also for use by the meat and poultry industries, private sector accredited veterinarians, and producers.

Multi-compound laboratory and on-site testing methodologies are also being developed. These resource-saving tests will permit laboratory technicians and plant personnel to test for the presence of a variety of drug and chemical residues. They will determine the presence of certain chemicals in the sampled product and, in some cases, will also be able to identify the concentration.

The following information lists the various rapid tests and immunoassays that are currently undergoing development or field testing.

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RAPID TESTS AND IMMUNOASSAYS

PYRETHRINS:

FSIS has developed an enzyme immunoassay under an interagency agreement with the Lawrence Livermore National Laboratory (LLNL), U.S. Department of Energy, Livermore, California. This is a competition enzyme-linked immunosorbent assay (c-ELISA) for synthetic pyrethroid insecticides including permethrin, deltamethrin, and cypermethrin (Stanker et al. 1989, J. Ag. Food Chem. 37:834). In the FSIS Eastern Laboratory, Athens, Georgia, this procedure is now available in a 96-well microtiter plate format for the detection and determination of the pyrethroids in animal and poultry fats.

Using the same antibody reagents, a "swipe" test kit is being developed for FSIS at the Lawrence Livermore National Laboratory under a new agreement. This screening kit will be designed for use by inspectors in the field for the detection of pyrethroid insecticide residues on plant equipment surfaces. Thus, contact exposure of meat and meat products to these chemical residues could be minimized.

DIMETRIDAZOLE:

An enzyme immunoassay in the 96-well microtiter plate format has been developed for FSIS at the LLNL. This c-ELISA will detect dimetridazole, hydroxydimetridazole, and ipronidazole. Further evaluation of the method in the FSIS Midwestern Laboratory is planned.

HEPTACHLOR - CYCLODIENE INSECTICIDES:

FSIS and the LLNL have completed developmental work on a c-ELISA for the detection and determination of cyclodiene insecticides including heptachlor, heptachlor epoxide, chlordane, and endosulfan. This 96-well microtiter plate assay format will provide FSIS laboratories with increased sample throughput capability. Further evaluation of the method in the FSIS Western Laboratory and development of a test kit format for field application are planned.

IVERMECTIN:

An enzyme immunoassay for the detection of ivermectin is being developed for FSIS at the U.S. Environmental Protection Agency laboratories in Las Vegas, Nevada, under an interagency agreement. When completed, further evaluation and implementation of the method will be done in the FSIS Eastern Laboratory.

BENZIMIDAZOLES:

An enzyme immunoassay for the determination of the benzimidazole anthelmintics is being developed for FSIS at the U.S. Department of Agriculture, Agricultural Research Service, Western Regional Research Center, Albany, California.

EVALUATION OF COMMERCIAL TEST KITS

FSIS is presently evaluating four immunochemical rapid screening test kits. Three of these kits are manufactured by Immuno Systems, Inc. The fourth kit is manufactured by Enzytec, Inc.

TRIAZINES (Immuno Systems, Inc.):

This test kit detects the four triazines atrazine, propazine, terbuthylazine, and simazine in a nonspecific manner. Laboratory evaluation has shown that triazines can be detected at one-half of the tolerance level (20ppb). FSIS has planned validation studies for this test kit during FY 1990.

CYCLODIENES (Immuno Systems, Inc.):

Using this test kit, the chlorinated hydrocarbons dieldrin, aldrin, endrin, heptachlor, chlordane, and endosulfan can be detected at one-half of the tolerance level (300 ppb).

Both the triazine and the cyclodiene kits have been developed by the manufacturer for testing feed, soil, and water. However, the FSIS Eastern and Midwestern Laboratories have adapted them for application to animal tissues.

0RGANOPHOSPHATES/CARBAMATES (Immuno Systems, Inc.):

This is a cholinesterase inhibition test for organophosphates and carbamates. Initial evaluation of this test tube format kit by FSIS scientists has not been very successful; however, a further evaluation is planned.

ALACHLOR (Immuno Systems, Inc.):

This test kit is being marketed by the manufacturer for the nonspecific detection of alachlor, metolachlor, and metalaxyl in water. FSIS has not yet evaluated this product for application to meat and poultry.

ORGANOPHOSPHATES/CARBAMATES (Enzytec, Inc.):

This is also a cholinesterase inhibition test for organophosphates and carbamates. This kit uses a simple "ticket" format. It is similar to a dipstick test. A disc on one end of a ticket is impregnated with the enzyme cholinesterase, while another disc on the opposite end contains a chromogenic substrate. The test can detect several pesticides

including malathion, parathion, methyl parathion, diazinon, carbaryl, and aldicarb. Currently, the scientists at the FSIS Western Laboratory are evaluating this test kit.

FSIS will be conducting laboratory and field studies with three of the commercially available rapid tests. The Agency will initiate evaluation of a simple, rugged chromatography system for use with rapid in-plant tests and test a clinical chemistry chromatography system for application to pesticide and veterinary drugs.

The Chemistry Division of FSIS has also contracted with the University of Washington Center for Process Analytical Chemistry for the design and development of a computer-assisted residue testing system (CARTS). CARTS is a field-portable instrument that can automate a wide range of on-site tests, such as screening for aflatoxins, pesticides, herbicides, and veterinary drugs. CARTS has the potential to not only improve test sensitivity, accuracy, and reproducibility, but also to improve data quality control, and to transmit results to a central data collection facility, or to existing FSIS databases such as RVIS by keystroke. This transmission eliminates the need for inspectors to fill out forms by hand. The instrument will be field-tested in FY 1990 against the SOS test.

The Agency has also recently published an Advanced Notice of Proposed Rulemaking for a formal evaluation process for tests submitted to FSIS for approval. Such an evaluation process would speed up the approval process and encourage commercial development of rapid tests.

8. INCREASED SAMPLE SIZE FOR CHEMICAL RESIDUE CONTROL

NAS Recommendation

The NAS recommended an increase in the sample size of FSIS residue monitoring activity to improve the Agency's ability to prevent consumer exposure.

FSIS Response

The residue monitoring sample is designed to provide information on incidence, not to prevent exposure. It is unrealistically expensive to change the focus from monitoring to prevention of exposure. The Agency agrees that it needs, and intends, to improve the management of information generated in the monitoring activity to enable it to focus its integrated set of residue control activities on prevention. The Agency also plans to improve the focus of its testing in high-risk animal populations to diminish the likelihood of adulterated product entering the food supply from these sources.

Recent Events

In 1986, FSIS began development of a nationwide interagency database, the Residue Violation Information System (RVIS). This system was fully operational by October

of 1988 and is accessible around the clock to FSIS and the FDA for documenting, compiling, tracking, and reviewing residue violation case activities. This kind of information base has improved the Agency's oversight capabilities, facilitated the coordination of interagency actions, and enhanced all aspects of residue case management.

The Agency is currently working to upgrade the Compound Evaluation System, exploring methods of grouping compounds, and improving its risk assessment methodologies.

FSIS is also continuing to work with the Extension Service and industry groups to encourage producers and packers to make residue prevention a part of all stages of animal production.

In March 1990, representatives from FSIS and the FDA attended a workshop facilitated by an internationally recognized expert in disease control program planning. The effort resulting from this workshop is expected to culminate in the development of an improved control strategy that will enhance residue sampling effectiveness.

9. RISK-BASED INSPECTION: APPLICATION OF HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP)

NAS Recommendation

The NAS recommended emphasis on hazard analysis and critical control points (HACCP), limiting inspection where the historic yield of violations is low and where public health risks are negligible.

FSIS Response

In response to this recommendation and the recommendations contained in the NAS report *Poultry Inspection: The Basis for a Risk Assessment Approach*, FSIS began pilot testing the use of HACCP at a poultry processing plant in Puerto Rico. The HACCP concept was applied to poultry inspection by focusing on points in the production process where microbial contamination could occur, and determining methods to assure that contamination was controlled. In the ongoing Bacteria Control (BC) project, hazards of a bacterial nature are identified at various points in the production processes; controls to the processes are developed at those points which permit control of the bacterial loads of the final product.

Since the BC project began in November 1987, approximately 2,000 bacterial samples have been collected and analyzed. These samples have been taken from farm operations and at the plant. The samples are analyzed for aerobic plate count, Enterobacteriaceae and *E. coli* counts, and the presence or absence of *Salmonellae*. Baseline data have been collected at critical control points within the processing operations. As

various control measures are tested, their effectiveness is determined by comparison with this baseline.

In 1988, the BC project concentrated primarily on control measures within the plant. In 1989, the primary area of focus was on farm operations. At the conclusion of the BC project, FSIS will be ready to issue a final report. This report may provide the basis for (1) minimum standards and procedures for poultry production processes at identified CCPs, (2) the possible basis for the development of other BC programs, or (3) may lead to additional BC studies at other poultry companies.

Recent Events

See #s 2 and 4 above.

10. DOCUMENTED ASSURANCE OF SANITATION

NAS Recommendation

The NAS recommended that there be documented assurance, backed by substantial compliance enforcement, of the sanitary wholesomeness of all meat and poultry products.

FSIS Response

FSIS designed and implemented the Performance-Based Inspection System (PBIS), which consists of four new inspection tools: the Inspection System Guide (ISG), automated inspection schedules, classification and documentation of plant deficiencies, and a corrective action system which incorporates progressive enforcement procedures that can result in withdrawal of inspection when necessary.

PBIS classification and documentation procedures are built around the Process Deficiency Record (PDR), a written evaluation of the Critical Control Point (CCP) checks which directly relate to the plant's condition at the time of inspection. The results of inspection are provided to plant operators on a PDR containing written descriptions of deficiencies and signed by the inspector-in-charge. The plant operators are requested to describe in writing the corrective and preventive actions they will take to remedy the deficiencies. The findings of inspection checks are also entered into the Agency's PBIS database and become a part of the plant's performance history. Expanded use of directed chemical and microbiological sampling as a supplement to in-plant inspection of sanitation and finished products is an additional and integral part of PBIS. PBIS also relies on full use of program withdrawal authorities for chronic deficiencies that should result in a much stronger inspection program.

Recent Events

Additional Agency emphasis on documented assurance of proper sanitation is reflected in the FSIS Regulatory Programs' activity. While the major focus of the Program Review activity is not on sanitation checks, Regulatory Programs' staff tracks the Agency's progress in assuring that all aspects of meat and poultry inspection programs are carried out effectively. Using the Inspection System Guide (ISG), reviewers visit inspection system locations throughout the country to observe products, inspection techniques, slaughter and processing procedures, product environments, and records. Reviewers evaluate critical inspection control points, including the sanitation of facilities and equipment. This, in effect, is an audit of inspection effectiveness. Reports on the results and findings of these audits are made to senior FSIS managers. Serious conditions discovered during audits result in the issuance of a Review Deficiency Report (RDR) to the plant involved. RDRs focus immediate attention on the violating plant, where corrective actions are undertaken by plant personnel in cooperation with FSIS inspectors.

Regulatory Programs has completed a Special Project on Preoperational Sanitation in poultry slaughter plants. Inspection Operations addressed the resulting recommendations and took steps to (1) assure uniformity for applying FSIS Directive 11,040-1, (2) implement red meat slaughter preoperational sanitation which parallels the program in poultry slaughter, and (3) review all plants for compliance with sanitation requirements.

In October 1989, an FSIS task force was convened to develop an amendment to the Inspection System Guide to cover slaughter operations.

In January 1990, a task force was established to develop a corrective action plan, similar to the plan used in processing, for progressive enforcement of slaughter deficiencies. These initiatives will bring slaughter operations in line with processing in the areas of documentation, compliance enforcement, and assurance of the sanitary wholesomeness.

FSIS has also initiated a Sanitation Emphasis Project which is intended to have industry take responsibility for the sanitation of its plants so that FSIS inspectors can assume the role of regulator rather than quality control supervisor. In addition to developing training and information programs for industry workers, FSIS plans to ask the industry to establish: company policies that encourage good sanitation practices; better slaughtering and dressing practices that avoid contamination; aggressive use of new technologies to monitor sanitation; better design of equipment and plants; and an adequate research budget to study problems in plant and product sanitation.

11. ENHANCED ENFORCEMENT CAPABILITY

NAS Recommendation

The NAS recommended that FSIS seek enhanced enforcement capability to impose a broad range of penalties upon violators, including refusal to inspect and approve their products.

FSIS Response

FSIS sought and obtained expanded enforcement authority. As part of the Processed Products Inspection Improvement Act legislation, Congress amended Section 401 of the Federal Meat Inspection Act (21 U.S.C. 671) to broaden the authority of the Secretary to withdraw inspection from plants which pose a threat to the public health or -- pending hearings -- temporarily keep individuals convicted of designated offenses (e.g., the intentional adulteration of food, bribery, and extortion) from taking part in the operation of meat plants.

Recent Events

FSIS initiated three programs, the PBIS Corrective Action System, Establishments Requiring Additional Inspection Effort (ERAIE), and Intensified Regulatory Enforcement (IRE) during the last decade to enhance the enforcement capabilities of the Agency. FSIS is in the process of integrating these programs under one Progressive Enforcement Action system. Under the new integrated system, establishments that are unable or unwilling to comply with FSIS regulatory requirements will move through a series of enforcement actions that can culminate in withdrawal of inspection.

Work is currently underway to develop an action plan for progressive enforcement for slaughter deficiencies similar to the plan used successfully in processing operations. When this work is completed, slaughter operations will be standardized with processing operations with respect to documentation, compliance enforcement, and assurance of the sanitary wholesomeness of all meat and poultry products.

12. INCREASED TECHNICAL CAPABILITY

NAS Recommendation

The NAS recommended adequate resources to ensure continued improvement of FSIS' technological base, including the development of new inspection technologies to reduce cross-contamination of carcasses and more comprehensive assessment of toxicological hazards.

FSIS Response

FSIS requested from Congress funds to support a methods development activity. The Agency continued to use the Agricultural Research Service (ARS) to perform that research ARS was willing and able to do in a timely fashion. In the next fiscal year following the release of the NAS report, FSIS asked for and was granted $2 million in additional ARS research. Congress specifically directed ARS to use these funds to support FSIS research needs. As a result of this support, new ARS research projects supporting FSIS requirements jumped from one in 1986 to five in 1987.

Recent Events

As a direct result of the FSIS response to the NAS recommendations, ARS research projects directly supporting FSIS needs rose each year from 1986 to 1989. A peak level of six new projects were begun in 1989, at a directed funding level of $6 million.

The Agency continues to add to its inventory of rapid tests. The technology has expanded from bacterial inhibition tests for antibiotic residues to enzyme immunoassay technology, and the use of genetic probes for the identification of microbial strains. Some research is being conducted on the application of electronic scanning to the inspection process. The use of ultrasound, X-rays, near infrared light, visible reflectance, and machine vision are all under consideration.

For laboratory analytical testing, robotics have been introduced, and supercritical fluid extractions are being explored as a universal mechanism for preparing samples for analysis. Also, computerized thin-layer plate scanning and data transmission have been developed for in-plant testing.

In addition, several new analytical method research projects were submitted to ARS in FY 1990 with the objective of expanding FSIS residue testing capability. The projects are a blend of requests for improved laboratory and in-plant testing systems that focus on reducing the time and effort to perform residue tests. Supercritical chemistry and computer-assisted testing systems are also being developed through university scientists.

13. INITIAL AND CONTINUING EDUCATION

NAS Recommendation

The NAS recommended a mandatory system of initial and continuing education for inspection personnel that emphasizes food science, food technology, pathology, and public health, combined with a recertification program.

FSIS Response

FSIS already had in place a mandatory system of initial and continuing education for inspection personnel at the time of the NAS report. For instance, FSIS has a staff of approximately 38 full-time personnel at Denton, Texas, and at Texas A&M University to develop and deliver training to approximately 1,600 inspection and management personnel per year. Through the training center at Texas A&M, FSIS supplies training for approximately 400 Agency veterinarians and 1,200 food inspectors, industry personnel, state and foreign inspectors, and supervisors. The combined annual cost of the various types of training that the Agency provides is in excess of $5 million.

The FSIS Career Development Program fosters planned and systematic career development for FSIS employees throughout their careers to meet the requirements of their positions. FSIS provides special Veterinary Medical Officer (VMO) refresher courses for the Agency's best VMOs at designated training sites throughout the country. These training courses last for a full year. Also, a new refresher course for VMOs, called the Advanced VMO Program, is being conducted in conjunction with the Texas A&M Veterinary School.

The FSIS program also provides for accelerated training to meet qualification requirements for placement in other inspection positions and occupations. This aspect of FSIS training is best illustrated by the fact that 67 of the 219 food technologists who are currently working for FSIS have been trained by the Agency. FSIS is also training personnel to fill critical vacancies that cannot be filled by private recruitment, such as through the Pathology Training Course and the training program in science specialties offered at the University of Georgia and the sabbatical training in public health and epidemiology at The Johns Hopkins University in Baltimore, Maryland.

Recent Events

FSIS recently dedicated the Donald L. Houston Center for Meat and Poultry Inspection Sciences at College Station, Texas, a modern, well-equipped training facility that will serve as the centerpiece of FSIS training programs and initiatives. The training center houses the national training program for Federal meat and poultry inspectors. The training courses and materials, which had been developed at the former training center at Denton, are now being augmented by new modules developed with the assistance of the Texas A&M faculty. The center is able to provide specialized education in food chemistry, risk analysis, veterinary pathology, statistics, and computer science. University and FSIS instructors share the instructional tasks at the new center.

14. SUBSTANTIAL SCIENTIFIC AND TECHNICAL STAFF

NAS Recommendation

The NAS recommended that FSIS develop a substantial scientific and technical staff of respected scientists who would play a substantial consultative role in the development of policy.

FSIS Response

FSIS has undertaken other initiatives to raise the level and degree of influence of its scientific and technical staff as explained in #s 12 and 13 above.

Science has always played a major role in the meat and poultry inspection program. The Agency uses science to study changes in its policies and procedures and to gauge compliance with its laws and regulations. Within FSIS, the role of science continues to grow.

Recent Events

The Agency has created a new position, Special Assistant for International Science Liaison, in the Office of the Deputy Administrator for International Programs. The incumbent in that position seeks to facilitate the use by the Agency of new technologies available in foreign countries and to encourage the development of new innovations by foreign scientists through the use of PL-480 monies that might be used in the United States.

The Agency has reorganized its Science program to assure that the views of the FSIS Science laboratories are included in Agency decisionmaking. Through a newly-created position at the Assistant Deputy Administrator for Science level, the FSIS laboratories have become a part of the Agency's decisionmaking team as new innovations in laboratory capabilities are made a part of the decisionmaking process.

The Agency now offers a program to train Agency personnel in difficult to recruit areas such as microbiology, information resources management, and public health. Training takes place on the campus of the University of Georgia and lasts for one year.

The creation of the National Advisory Committee on Microbiological Criteria for Foods, which greatly augments the Agency's access to scientific and technical advice at the decisionmaking level, is a direct outgrowth of the NAS recommendation.

FSIS also works directly with the Codex Alimentarius and other international organizations to utilize scientific information in developing harmonized food safety regulations and facilitating the resolution of trade disputes.

15. STANDING ADVISORY PANELS

NAS Recommendation

The NAS recommended the presence of standing advisory panels composed primarily of outside experts to provide consultation on both policy and practices regarding meat and poultry safety.

FSIS Response

At the time of the NAS report, FSIS had already convened the Meat and Poultry Inspection Advisory Committee. The National Advisory Committee on Meat and Poultry Inspection is a statutorily-mandated advisory committee. The Secretary of Agriculture must consult with the Committee prior to the issuance of product standards and labeling requirements and on matters affecting the operation of Federal and State inspection programs. The 13 members represent the meat and poultry industries, academia, producers, Federal and State government officials, and consumers.

In addition, the Agency has contracted with a panel of scientific and technical experts outside USDA to provide counsel and technical critique for the duration of the Bacteria Control project being conducted in Puerto Rico and discussed in # 9 above.

Recent Events

The National Advisory Committee on Microbiological Criteria for Foods was established in response to the NAS recommendations. The Department of Health and Human Services' Food and Drug Administration (FDA), FSIS, the Department of Commerce's National Marine Fisheries Service, and the Department of Defense's U.S. Army NATICK Research, Development and Engineering Center (NATICK), requested NAS' guidance on how agencies could best develop uniform and coordinated approaches to assess the safety and wholesomeness of the Nation's food supply, including criteria for microorganisms that indicate whether foods have been processed using good manufacturing practices.

The 25 members represent Federal and State regulatory agencies, the scientific community, the food industry, academia, and consumer interests. An *ad hoc* working group was recently convened on *Listeria monocytogenes*. The working group will be providing recommendations to the sponsoring agencies on the best approach to control this pathogen.

Work is currently underway to establish an additional advisory committee that would consult with Agency scientists on residues. The envisioned Residue Advisory Committee would be modeled on the successful Microbiological Advisory Committee.

16. INTERAGENCY LIAISON

NAS Recommendation

The NAS recommended that there be strong liaison among FSIS, the Centers for Disease Control (CDC), the Food and Drug Administration, and relevant animal health agencies at the Federal, State, and local levels to ensure that no hazards are overlooked.

FSIS Response

FSIS agreed with the NAS recommendations. The inspection and monitoring of animal health is overseen by a vast collection of laws and regulations that have accumulated for more than a century, resulting in a program with splintered and overlapping jurisdictions. Thus, in order to carry out its legal mandates, FSIS must rely on many other organizations for a wide variety of services and support. A few examples are listed below.

- **Food and Drug Administration** establishes tolerances for many chemical residues, food additives, and drugs used in animal husbandry; investigates known or suspected illegal use of drugs on the farm.
- **Department of the Treasury** performs customs inspection of imported meat and poultry products.
- **Environmental Protection Agency** sets standards for clean water, sedimentation, chemical and biological hazards, as well as for the potential reuse of water by meat and poultry plants.
- **Department of Defense** sets standards and specifications for product destined for military installations and establishes procedures for the utilization of USDA veterinarians in times of disaster.
- **Department of Labor-Occupational Safety and Health Administration** sets health and safety standards in meat and poultry plants.
- **Department of Energy** establishes standards for energy utilization in plants.

This does not begin to exhaust the complex mosaic of interrelationships that are necessary to carry out inspection effectively. There are cooperative agreements with individual States, independent agreements with foreign countries on regulatory programs, liaison with the European Community, participation in the Codex Alimentarius Commission for the development of international food standards, and more. The NAS recognized that virtually nothing is done today in inspection that does not rely to some extent on a myriad of other organizations.

Recent Events

In order to provide for even better and stronger liaison with other public health regulatory agencies, FSIS has taken two approaches. One is the establishment of the Microbiological Advisory Committee, which has representatives from CDC, FDA, Department of Defense, and the Department of Commerce, as well as State and local representatives. Information pertaining to public health is regularly exchanged through this forum. Additionally, senior policy officials of FSIS, FDA, and the Environmental Protection Agency (EPA) are meeting approximately every six months. The meetings are used to exchange information on emerging issues that affect the agencies.

The other approach is to work with other regulatory agencies that have related responsibilities in the area of residue enforcement. The Agency's residue enforcement strategy is largely an interagency activity involving USDA's Extension Service and FDA. When positive results from tests for drug and chemical residues are found in animal or poultry tissues by an FSIS laboratory, FDA officials are notified for the purpose of initiating enforcement actions against growers for possible violation of FDA statutes. Additionally, Extension Service personnel are notified so that they can work with growers to improve their safe usage of animal drugs and pesticide chemicals to avoid future residue contamination.

Several joint Agency activities are currently being undertaken under the umbrella of a Tripartite Memorandum of Understanding agreed to by USDA, FDA, and EPA in 1985. For example, information on residue violations and follow-up activities is shared through an on-line information system known as the Residue Violation Information System (RVIS) by FSIS and FDA headquarter and field offices. FDA and EPA are also represented on the Science Advisory Team for the FSIS National Residue Program, and FSIS is working with EPA in revising EPA's regulations that address chemical residue analytical methodology.

FSIS has also established an interagency **Animal Food Biotechnology Information Exchange Group** for exchanging technical regulatory information on developments in biotechnology. Representatives attend from FDA, EPA, APHIS, and FSIS.

17. RAPID AND FLEXIBLE DATA SYSTEMS

NAS Recommendation

The NAS recommended that FSIS make substantial use of rapid, timely, and flexible systems (probably computer-based) to acquire, transfer, analyze, and make more widely available data related to inspection and to meatborne hazards.

FSIS Response

FSIS responded to this recommendation by immediately seeking additional funds from Congress to carry out its existing plan to augment its data systems. The plan consisted of the following steps:

1. Improve the design of its databases.
2. Improve the Agency's capability in the interpretation of data for management decisionmaking.
3. Improve the quality of information and its accessibility to FSIS managers.
4. Improve the collection and timeliness of data.

By FY 1987, FSIS had received $2 million in additional funds specifically allocated to this project. Work began immediately to develop, field-test and implement a nationwide, automated information system for the collection, analysis, and use of inspection data. By 1989, this and other related projects had evolved into the Performance-Based Inspection System that was scheduling inspection tasks nationwide and recording the results.

Recent Events

By the end of FY 1989, over $6 million of development and implementation funds had gone into PBIS. The system now documents the performance of more than 1 million inspection tasks per month. An entire array of management reports is now available, on an Area-by-Area basis, showing the current status of plants under Federal inspection.

FSIS is presently working on a system for aggregating the results of inspection on a Region-by-Region basis and on a national basis. The system allows for reports to senior managers that will enable them to analyze results and determine trends in inspection throughout the entire country.

Substantial investments are also being made in other Agency database systems. One such system is called the Common On-line Reference for Establishments (CORE). The CORE system is an interactive system that serves both as an information collection and maintenance system and an information retrieval system for data on meat and poultry plants under mandatory Federal inspection. Such information includes the location of the plant, its status, the operations it performs, any special services it has requested, the ownership of the plant, and its special mailing codes. Primary uses of CORE are mail distribution, source data for printing the Meat and Poultry Inspection Directory, and retrieval of information. CORE also acts as a common link among various Agency systems, such as the Labels Information Systems (LIS) and the Review

and Evaluation Information System (REIS), thereby offering users easier information access across various databases.

Other automated systems which have been installed include the Microbiological and Residue Computer Information System (MARCIS), the Animal Disease Reporting System (ADRS), and the Protein-Fat-Free (PFF) System. In 1990, the Document Issuance and Library System (DIALS), a database of meat and poultry regulations, directives, and notices, will provide information to interested users in electronic form.

TESTIMONY OF DAVID CARNEY

before the

SENATE AGRICULTURE SUBCOMMITTEE ON

AGRICULTURAL RESEARCH AND GENERAL LEGISLATION

hearings on

THE ADEQUACY OF THE SCIENCE BASE FOR

USDA'S FOOD INSPECTION PROGRAM

July 20, 1989

STATEMENT OF DAVID CARNEY, VICE CHAIRMAN,
FOOD INSPECTORS UNION, AMERICAN FEDERATION OF
GOVERNMENT EMPLOYEES

Mr. Chairman and members of the subcommittee, thank you for inviting my testimony to the Agricultural Research Subcommittee on the adequacy of the United States Department of Agriculture's scientific program as a foundation for federal meat and poultry inspection. My name is David Carney. I am a GS-8 food inspector with the USDA Food Safety and Inspection Service (FSIS). I also serve as the Vice Chair of the Food Inspectors Union, American Federation of Government Employees. I am testifying today as a citizen, not as a representative of the Department of Agriculture.

One opening observation is in order. Some observers have contended that scientific advances are the way to eliminate human beings like inspectors from food safety responsibility. As a result, they have assumed that inspectors and their union are defensive about scientific improvements, or see it as a job threat. Those statements are the opening lines for a food safety fairy tale. Inspectors want stronger science at USDA, because we need it to do our jobs.

Most significant, anyone grounded in reality knows that onsite inspectors and advanced scientific technologies serve different, not competing functions. The public needs both. For example, scientific breakthroughs such as rapid laboratory tests can never be a substitute for common sense sanitation. The tests only tell us the effects of a sanitation breakdown. Inspectors are there to enforce the law and prevent the public health threats tests only can detect. To analogize, we have traffic police to enforce laws preventing accidents, not to confirm they have occurred. Similarly, any sound business leader will confirm that quality control inspectors are not enough, even if they catch all the defects for which they check. Quality must be built into the process. So must sanitation.

Similarly, there are no rapid tests in sight to check for all the various contagious infections and diseases whose symptoms federal inspectors regularly detect, such as listeria and tuberculosis. Since we often take action against obvious cases over vehement company objections, it is clear that inspectors will be needed for a long time. We have no reason to feel threatened by science.

USDA'S COMMITMENT TO SCIENCE IN NAME BUT NOT DEED

Unfortunately, even if we were defensive, there is not enough serious science at USDA to be threatening. Recently whistleblowers have exposed that USDA uses the language of the scientific method but skips the substance. Qualified scientific professionals charge that the agency has not done systematic advance studies to determine the effects of new inspection systems before they are introduced. There hasn't yet been a thorough USDA study of the effect that line speeds have on contamination, although USDA has paved the way as line speeds doubled and tripled in some instances. There aren't studies of the impact that new

technologies -- like eviscerating machines and feather pickers -- have on contamination before USDA approves their use. New environmental technologies must go through an Environmental Impact Statement process. By contrast, new food technologies effectively get a blank check from FSIS. In other words, USDA is engaged in scientific blind man's bluff before switching food safety systems.

Whistleblowers have charged that scientific research is censored if it could threaten public confidence in the safety of meat and poultry; and that USDA peer review is an insult to normal professional standards: the agency buys the reviewer's opinions and then gags them in case they deviate from the party line. They added that the agency uses unvalidated methods to test for salmonella and other contamination and that the testing methods are rigged to assure that the results won't alarm the public.

Critics have exposed how the same problems apply to the statistical sampling programs that FSIS uses to switch for checking every carcass. The sampling systems use the language of the statistics but butcher the profession's standards. The samples are so small that they don't even cover the various different sources of poultry or cattle, which means the dirty flocks or lots may be missed entirely. The sampling reviews have built-in handicaps that make it nearly impossible to flunk. Even then the USDA sample won't trigger corrective action, unless the company flunks itself in a second opinion after choosing its own sample. In my experience and that of all inspectors I know, that has never happened.

From the perspective of inspectors and veterinarians in the field, the critics are right on target. Every day we have to cope with the results of USDA's program of non-science. Five examples should illustrate my point.

1) Since 1986 USDA has said it was switching to food technologists as a more scientific substitute for inspectors at processing plants. But all FSIS has done is change the name, not the functions in practice. The food technologists don't do anything significantly different than traditional processing inspectors. They handle and review the same documents as always.

2) USDA scientists or managers never bother to consult with the field inspectors <u>before</u> changing the inspection system. They don't ask us the questions needed to know how scientific studies should be set up. Ivory tower science doesn't work for studies of filth. The studies never will be realistic until the bureaucratic scientists are willing to talk first with the field personnel who get their hands dirty.

3) A lot of times there simply aren't any studies at all, good or bad. For example, last November USDA proposed to implement its Streamlined Inspection System-Cattle without ever conducting a study of how the pilot system has worked. The only study at all is one from 1984 that involved a related system where the lines weren't speeded up, which is the main point of SIS.

4) Field supervisors regularly announce bizarre, subjective changes in inspection standards. For example, inspectors are not supposed to condemn poultry with air sacculitus -- a disease that fills their lungs with pus -- except in "extreme cases." We are supposed to approve cadavers -- poultry that were put in the scald tanks before their hearts stopped beating -- unless they are "bright red" from the hemorhhaging. When bewildered inspectors ask for an explanation, the managers are unable to explain either precisely what the new rules are, or why they will work as well as traditional approaches. To the inspectors in the field, it appears that USDA's public health standards are being changed by whim. That is devastating for our morale and pride in our professionalism. The public deserves better.

5) The bottom line is the results in the field. The bottom line for USDA's non-science program is that the public never before has received poultry that's dirtier or beef that's more diseased. For example, as line speeds have increased, so have levels of salmonella contamination. There's almost a direct relationship. I won't elaborate, because there already has been so much publicity about the disgusting products that now regularly get USDA's seal of approval. The increase in contaminated products should end any serious debate, however. FSIS has to do better, and better science is where it all starts.

MISMANAGEMENT OF SCIENTIFIC RESOURCES

Field personnel don't always have to wait for filthy and diseased products to see the symptoms of a scientific breakdown at USDA. Sometimes we can observe the mismanagement as it occurs. For example, we do not receive adequate scientific training as a foundation for our inspection duties. Recently USDA invested a major portion of the agency's budget to establish a new training center at Texas A&M, a major agricultural school. Unfortunately, while we now get to attend training sessions at a college campus, the course materials and other contents haven't changed. The only thing that is more academic is the rooms. Again, USDA has adopted impressive cosmetics but no more.

Second, we're not using the best facilities and technologies available. Industry laboratories make USDA's scientific resources look like clubs and stones. The plants routinely test their products in their own modern laboratories and get the results within 48 hours. Inspectors, on the other hand, have to wait two to three weeks to get back laboratory results from USDA-approved facilities. By then the food is out to market and often has been consumed. USDA can't use the plant facilities, and our chances of being onsite to catch the industry cheating range between slim and none. What this means is with respect to science, federal inspectors are at the industry's mercy. The plants control their own destiny.

Third, FSIS management doesn't even use the scientific tools that are available. I recently had an experience where bureaucratic headquarters decisions undercut the little science we could have used to protect the public. I recently helped catch some 8,100 pounds of SIS-approved poultry that were processed despite being covered with abscesses. Agency management intended to let the product out to the public after determining that the abscesses were adverse drug reactions rather than disease symptoms. But management didn't let us hold off until laboratory tests revealed whether the drugs that caused the abscesses were illegal.

The obvious conclusion is that while we need more resources for an improved science program at the Department of Agriculture, throwing more dollars into the current system will just be wasting the taxpayers' money. My recommendations are as follows.

1) We need a scientific program with integrity. USDA uses the Madison Avenue, public relations approach to science. The public is not buying it.

2) We need a scientific program that doesn't avoid the hard issues, and isn't aloof from the field personnel whose insights are unique and badly needed.

3) Finally, we need agency management that is willing to wait for scientific results before making major policy decisions on inspections systems of condemnation of suspect products. Today the agency management runs away from science whenever it could undercut the party line.

Mr. Chairman, when we have solved those problems we will be ready to effectively use more scientific research and development money to make America's food supply even safer. Not before. Thank you for inviting my testimony. My attorney and I will gladly work with your staff to follow through on this testimony. As part of my ongoing willingness to help, I request that the committee submit certain questions to FSIS that other inspectors have asked me to pass along for agency response.

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PREPARED STATEMENT OF JAMES L. MARSDEN, PH.D., VICE PRESIDENT, SCIENTIFIC AND TECHNICAL AFFAIRS, AMERICAN MEAT INSTITUTE, ARLINGTON, VA

My name is Dr. James Marsden, vice president, Scientific and Technical Affairs for the American Meat Institute (AMI). AMI is the national trade association representing meat packers and processors. Our members slaughter and process more than 80 percent of the meat products produced in the United States. AMI appreciates this opportunity to share our views on the current state of inspection technologies and the related research needed for continued improvement in meat and poultry inspection programs.

Since the passage of the 1906 Meat Inspection Act, AMI has been instrumental in directing or conducting research to keep industry practices and inspection regulations in step with developing technologies. We take this role seriously. We believe government inspection programs are necessary and that they provide assurance that meat and poultry products are safe and wholesome. The application of new science to meat safety and product development holds the prospect of revolutionary change in the years ahead. AMI and our industry intend to be on the cutting edge of this revolution.

Over the years, the majority of industry changes have been directed toward improved operating efficiencies and producing products that satisfy consumers desires for freshness, convenience and palatability. But during the past 15 years, a sharper focus on public health concerns has resulted in more emphasis being placed on product safety.

Product safety begins with a fundamental understanding of several complex interrelated factors such as live animal physiology, microbial behavior in raw and processed products and supercritical analytical techniques for proper evaluation of processing controls and product safety. These understandings emerge from research. For this reason, we are pleased this subcommittee is devoting attention to the critical research needed to help the USDA meat and poultry inspection program address a new era of food safety challenges.

To provide guidance for improving the meat and poultry inspection program, USDA commissioned the National Academy of Sciences (NAS) to examine the scientific basis of the nation's meat and poultry inspection program. Following release of the NAS report in 1985, AMI formed a special task force to review the major conclusions and recommendations. The full report of the AMI Special Task Force is included with my testimony.

AMI's Task Force generally agreed with the NAS recommendations that modern science and technology be used as a basis to allocate inspection resources commensurate with public health risks. Furthermore, the AMI Task Force expressed its firm belief in the ability of the industry and USDA to modernize the inspection system in a way that would provide maximum efficiency and consumer protection.

NAS outlined several characteristics of an optimal meat and poultry inspection program. Some of the more salient points included:

- Maximum use of plant personnel in process-by-process and day-to-day monitoring of critical control points with FSIS oversight to ensure compliance.
- An inspection system with different levels of intensity, reflecting the degree of public health risk at various stages in the process, the reliability of the monitoring system, the compliance history of the slaughterhouse or processing plant, and the special needs of the intended consumer.
- Emphasis on Hazard Analysis and Critical Control Points (HACCP), limiting inspection where the historic yield of violations is low and where public health risks are negligible.

Recent efforts by FSIS to modernize slaughter and processing inspection are consistent with NAS's general objectives for an optimal inspection program. Nevertheless, the Improved Processing Inspection (IPI) proposal designed for plants manufacturing prepared meat and poultry products and the Streamlined Inspection System (SIS) proposal for beef slaughtering plants were generally opposed.

Criticism varied widely but, due to a lack of overall understanding, the proposals were generally not viewed as strengthening the inspection program. In retrospect, the underlying problem may well have been USDA's inability to adequately communicate program benefits.

Throughout the planning process, USDA essentially maintained a closed door policy. Elements of the new inspection program emerged for public scrutiny only after agency decisions were seemingly carved in stone. The lack of meaningful input by the industry, government inspectors and public interest groups severely crippled USDA's ability to build a consensus for new workable inspection programs.

Further compounding the situation, some opponents of the new inspection programs, unfairly characterized the changes as industry deregulation with fewer inspectors that would endanger public health protection. The ensuing outcry, coupled with industry complaints about certain specifics in the proposal, created a poor environment in which to rework the proposal.

AMI continues to believe modernizing inspection is an absolute necessity. We strongly suggest that future efforts by the Food Safety and Inspection Program be accompanied by a public communication program that will clearly show the consuming public how the changes will improve meat safety.

The NAS committee devoted considerable attention to improved control of microbiological and chemical contaminants. These potential health hazards provide unique challenges to USDA and the regulated industry. Microbial and chemical contaminants do not lend themselves to the traditional inspection procedures that rely on physical inspection by sight, smell, and touch. Advanced diagnostic technologies must now be used to make decisions important to public health and safety.

Even though sophisticated detection methods are currently available, in many cases they are too time consuming to allow normal movement of products through the marketplace. Consequently, the industry has increasingly relied on preventative control programs based on sound science and a management commitment to build safety into each critical step of the process. These programs, commonly called Hazard Analysis Critical Control Points or HACCP, have become the watchword for process control.

Properly used, HACCP provides an effective tool to produce product in compliance with regulatory standards and significantly greater safety assurance to consumers than exists under current inspection programs. Traditional inspection programs tend to focus on detection and response to problems rather than relying on properly designed prevention programs. Control of critical points in the production process assures a safe end product and requires only monitoring by inspection personnel.

The success of a HACCP program depends on the underlying research that identifies critical points in the process and provides control procedures to determine if standards are met. FSIS has adopted HACCP in principle but has yet to recognize the concept in a general regulatory framework. AMI believes these programs, if more widely adopted, will significantly improve the meat and poultry inspection program.

To augment scientifically based inspection changes, AMI strongly urges this subcommittee consider an expanded research mission to support USDA's Food Safety and Inspection Service (FSIS) regulatory objectives.

Basic research programs within the Agricultural Research Service and Cooperative State Research Service are commendable but these long-range basic research programs are not often designed to satisfy short-term or immediate regulatory needs.

FSIS should have a greater ability to direct research dollars to specific agency objectives. Adequate facilities and personnel should be available for immediate regulatory responses to unexpected situations.

Controlling microbiological contamination of meat and poultry products is a primary concern for USDA and the regulated industry. Even under optimum conditions, bacteria will be present in the food chain.

Many microbial contaminants enter processing plants in or on livestock. New technology, developed in part by AMI research in carcass washing and decontamination procedures, offers practical means to reduce microbial contaminants. The USDA Meat Animal Research Center has conducted research in this area and is uniquely equipped to test new procedures, verify industry trials and assist FSIS in approving new microbial control methods in fresh meat and poultry. AMI urges increased research funding in the important area of microbiological control.

No area of new technology is changing more quickly than development of rapid bacteriological diagnostic tests. Three years ago, the detection of *Listeria Monocytogenese* bacteria required 2 to 3 weeks. Today negative results can be obtained in 48 hours. Furthermore, test methods can now detect one bacterium in a sample and each year new advances make last year's accomplishments obsolete.

Research to develop more rapid microbial detection methods is needed by the regulatory agencies and industry. Detection of microbiological pathogens in a matter of hours rather than days is essential. Funding to identify emerging pathogens of human health significance is equally important. Today, *Listeria Monocytogenese* is a primary concern to USDA and the industry, yet this organism was scarcely mentioned in the 1985 NAS study.

Contrary to prevailing public understanding, technical experts familiar with the science of food microbiology know a *zero* tolerance for microbial organisms is unreal-

istic. Nonetheless, these technical experts also know that properly designed processes and inspection procedures can further reduce exposure to these public health hazards. Current regulations run the gamut from being misdirected for their intended purpose to an overzealous zero tolerance approach. A real need exists to bring these divergent regulatory views into an appropriate balance that considers both consumer protection and existing industry manufacturing capabilities.

The excellent safety record of meat products suggests that complete elimination of all microbial pathogens is not necessary for public safety. In fact, many microorganisms are beneficial and an absolutely sterile food supply is not a desirable objective. The food manufacturers' objective is to control the growth of pathogenic microorganisms below levels that pose a negligible risk to human health.

The task of defining microbiological criteria for known pathogens is very complex. Nevertheless, USDA and FDA should be commended for undertaking this arduous task through the formation of an expert panel on microbiological criteria. These efforts, along with additional epidemiological and analytical research, can provide the basis for more effective food safety regulation.

Preventing chemical and biological residues from entering the meat and poultry supply is the other major food safety concern facing government agencies and the industry. Significant strides in residue prevention have been made in recent years but continued improvement is needed.

Most producer organizations have developed and encouraged implementation of onfarm quality assurance programs. These programs have provided tangible benefits and helped reduce residue violation rates significantly below levels experienced earlier in this decade.

History has proven that most efforts to prevent illegal chemicals and biological residues must be directed to the source of entry into the food production system. A system for animal identification that enables trace back to livestock producers is essential to identify the source of carcass residues. AMI concurs with this NAS recommendation and believes a sound identification system is necessary to establish responsibility to those individuals that market animals containing illegal residues.

Last year the Animal and Plant Health Inspection Service and FSIS took a significant step forward by publishing final rules to implement a mandatory swine identification program. AMI favors similar identification programs for all animals if the need for residue trace back becomes necessary. Research to develop more cost effective animal identification methods would assist effective residue and disease control efforts.

Furthermore, better rapid onsite test methods are needed to identify potential residue problems as early in the production system as possible. FSIS has devoted considerable resources to this area, but additional improvements are still needed. Rapid test should be developed to detect multiple residues and yield virtually instantaneous results.

Residue test methods that piggy-back on existing disease control programs are needed. The brucellosis eradication program is a case in point. Mature animals are currently blood tested at either the first central concentration point, such as livestock markets or at slaughter facilities. Rapid tests that correlate residue levels in the blood and the tissue could greatly enhance an effective residue prevention program. AMI believes an accelerated research program to develop and improve rapid residue detection methods would provide significant long-term benefits.

Finally, it is important to underscore that everyone in the food chain, including the ultimate consumer, plays an important role in food safety protection. Most foodborne illnesses stem from product abuse *after* manufacturing. All of the efforts made by the industry and government inspection can be negated if food distributors, retailers, food service, or consumers improperly store and handle meat and poultry products. AMI believes Federal agencies should strengthen not only their research capabilities but also improve their educational efforts to make food handlers and users more aware of their responsibility to protect the food they distribute or consume. Together we can make a safe meat and poultry supply even safer.

Mr. Chairman, that concludes my remarks. I will be happy to entertain the subcommittee's questions.

[The attached report "A Review of the NAS Study on the Scientific Basis for the Nations Meat and Poultry Inspection Program," follows:]

A REVIEW OF THE NAS STUDY ON THE SCIENTIFIC BASIS FOR THE NATIONS MEAT AND POULTRY INSPECTION PROGRAM

(Prepared by Special Task Force, American Meat Institute, Arlington, VA, October 8, 1985)

Overview of NAS Study

The National Academy of Sciences (NAS), received a request from the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA), to evaluate the scientific basis of current systems for inspecting meat and poultry in the United States. A committee appointed by the Food and Nutrition Board of the Academy completed their study in July 1985.

This request was made, in part, because FSIS is actively addressing various measure of accommodating changes away from traditional inspection methods (unchanged for nearly 70 years). An FSIS management system that provides for adaptability and flexibility as impacted by new technologies in animal agriculture and the U.S. meat industry seems to be appropriate; however, such changes need systematic evaluation relative to public health issues.

NAS was asked to address the following:

- Assess the scientific foundation for USDA's Meat and Poultry Inspection programs to determine its impact on the quality, quantity and health of livestock and on the character and degree of various risks to human health;
- Make a comprehensive analysis of different inspection strategies, including comparative risk assessment, to predict their impact on public health; and
- Make recommendations based on new developments in biological research and technology and in the inspection program to further enhance its effectiveness and efficiency while maintaining or improving the current degree of public health protection.

The NAS study generally concluded that:

- Consumers have a high level of confidence that meat and poultry products are safe and wholesome.
- New programs and procedures instituted by FSIS in slaughter and processing areas are not likely to reduce those aspects related to public health protection, however, such changes need to be well defined in terms of relevant public health issues.
- There is a very positive willingness to change at USDA/FSIS in order to provide short and long range policy management systems that accommodate new technologies.

In order to effectively implement these conclusions, the NAS study recommended that:

- Personnel skills within FSIS management should reflect an interdisciplinary concept such that no one profession (discipline) is dominate.
- Policies and programs should more adequately reflect what is and is not "critical" in terms of public health risk.
- These programs should clearly focus on identifying the source and risk of potential problems and establishment of management systems for prevention at the source.

Overview—AMI Task Force

Because of its commitment to active participation and positive leadership regarding governmental policies, the American Meat Institute established a special task force (August 1985) to review the NAS study.

General objectives of this task force were to emphasize those aspects of the NAS study that would benefit the industry and its consumers by addition to or deletion of inspection strategies, policies, programs and operations. Specifically, the task force was to provide inputs that would assist in establishing a more clear perspective and rationale for prioritizing key issues identified in the NAS study. It should be emphasized that these objectives focus on issues that would not reduce the very positive public health aspects of current and future FSIS programs as outlined in the NAS study.

The subsequent AMI Task Force report is organized into a series of key issues with narrative statements. These issues are grouped into broad-based categories reflecting policies, programs and operations.

Summary of Key Issues

A. The AMI Task Force concurs with the NAS study that in general consumers have a high level of confidence that meat and poultry products are safe and wholesome. This should be clearly recognized and reflects credit to FSIS, animal agriculture and the industry for their positive contribution to safety and wholesomeness of meat and poultry products.

B. We encourage FSIS to redefine inspection criteria on the basis of what is and is not critical from a public health viewpoint. The results of clearly defining what is and is not critical, via use of hazard/risk concepts, should be the deletion of obsolete requirements for slaughter and process inspection. Such efforts should be tied into a policy review and disposition management system that effectively deletes and updates requirements rather than layering in new requirements in addition to ones which may be obsolete or no longer applicable.

C. All efforts to reduce potential public health hazards, from chemical and biological agents, should clearly be directed to the source of entry (farm, ranch, feedlot). Risk assessment by a grouping of similar agents would be useful in pin-pointing specific problem areas. Identification of "hot spots" at the source with corrective action would, in our judgment, substantially reduce potential hazards. FSIS should be designated as the lead Agency for surveillance in such a manner that the present interagency involvement is better utilized and more clearly defined. There is no need to create a new agency to address this issue.

D. A system of identifying animals offered for slaughter is absolutely essential for any program designed to eliminate potential public health risks associated with chemical or biological agents. In this regard, the NAS study supports an AMI petition to USDA for mandatory identification of all swine offered for slaughter. Other types of livestock that are raised in less concentrated units than swine should also be subject to an identification system. Perhaps a required certification method by lot or common management group would suffice as a trace-back mechanism to the source for these kinds of livestock. It is a common practice in the industry to identify animals in lots or groups according to the source of purchase. For animals that change ownership several times through complex marketing channels, lot or group certification method for identifying these kinds of livestock may be appropriate.

E. To support new methods, systems and technologies for compliance-based versus traditional inspection, we encourage FSIS to establish a clearly defined and ongoing research mission. We endorse the NAS study which suggests that a regulatory agency such as FSIS should have a research mission and budgetary support. This need could be accommodated within existing USDA facilities and personnel.

F. To accommodate changes in technologies, methods and systems of inspection, we encourage FSIS to upgrade personnel skills and to reflect interdisciplinary principles such that no one specific discipline dominates the mix of personnel.

Public Health Hazards From Biological and Chemical Agents

A. We encourage the continuing consumer education efforts of FSIS and industry in developing and disseminating practical information regarding proper handling and end user preparation of meat and poultry products. A majority of foodborne illness are directly associated with improper heat treatment and/or temperature control of products by ultimate users.

B. Rapid diagnostic technologies that are economical to use in a pooled/lot sampling system should be a major focus of the agencies research mission. Diagnostic technologies from human medicine may be adapted to high speed line operations to automate some aspects of current ante and post mortem inspection requirements performed by "hands on" techniques.

C. We encourage the development of new technologies for decontamination during slaughter/dressing operations. These technologies should not be restricted by labeling and inspection procedures and they should apply to carcasses as well as parts (subprimal cuts, edible offal, etc.).

D. FSIS should clearly become the lead agency for surveillance of potential biological and chemical residues. Focus of surveillance should be through an animal identification and trace-back system to the source of livestock using group risk assessment technologies.

For example:

1. Require producers of livestock to identify that the animals marketed have been raised in compliance with all applicable laws and regulations relative to feed ingredients, therapeutic drugs and similar agents.

2. These animals would be identified at the point of sale (slaughterer, feedlot, order buyer, auction yards) according to lot or group reflecting common feed, veterinary treatment or exposure to other chemical agents.

3. Continue the surveillance of animals via the existing National Residue Program (NRP) with trace-back to source using animal identification documents. Increase sampling rates and frequency in a specific area when problems are encountered. The trace-back system must traverse Federal, State and local policies.

Any system for surveillance requires that some kind of "group risk assessment" be used to define what to monitor. Analytical methods have the capability to determine presence or absence of many chemicals, but that capability does not necessarily mean that all chemicals are hazards at levels detected. After all, the human body is nothing more than a "sea of chemicals surrounded by skin."

E. We encourage FSIS to use their scientists more actively in professional associations, research publications and teaching programs that relate to biological and chemical hazards. Agriculture schools are also encouraged to include such materials in their curriculum development programs for livestock and poultry husbandry.

Slaughter Inspection

A. We concur with the NAS study that FSIS instituted changes in slaughter inspection toward compliance-based methods have not reduced those aspects related to public health. These changes have been based on informal risk assessment and hazard analysis/critic control point concepts. Although these concepts may need to be formalized, they have been effectively used as a valid and rational scientific basis for changing policies. They are commonly practiced by the industry as well as FSIS. Any change should be carefully scrutinized with FSIS objectives clearly in mind.

B. Future changes in slaughter inspection (ante and post mortem) should be tailored to differences among individual plant needs based on species, age and type of animals slaughtered.

C. The NAS study strongly suggest that present methods of ante mortem inspection could be replaced with a sampling program of varying intensity. We also feel that this approach or one that takes into account the risk from type of livestock slaughtered should be given consideration. For example, the 0.3 percent of rejected animals may well be concentrated in those that are very mature chronologically. Plants which slaughter these kinds of animals may indeed require more intensive ante mortem inspection than those that slaughter younger animals.

D. We agree with the NAS study that inspection requirements not directly associated with public health hazards need not be conducted on the slaughter floor. Aesthetic conditions (abnormal skin condition of swine, arthritic joints, bruises, dislocated joints, broken bones, etc.) have little or no effect on public health risk. Their removal would often be more efficient during subsequent cutting operations. A compliance-based system similar to AQL that traverses slaughter and carcass fabrication would certainly enhance the concept of tailoring inspection requirements to specific plant needs. This should result in more effective and efficient use of manpower, reduce duplication of effort and not affect public health risk of meat and poultry inspection.

E. Disposition guidelines for slaughter inspection needs refinement of definition. The NAS study recognized this and our task force concurs. Further, a comprehensive study should be conducted of the public health risks associated with lesions and other chronic conditions requiring inspection under current policies. It may be that we are spending inordinate amounts of time looking for things that have no apparent human health risk.

F. We encourage the meat industry and FSIS to openly experiment with new slaughter/dressing methods which reduce contamination. These experiments and resulting technologies should not be hampered by restrictive labeling policies that may be counterproductive to use of new technologies.

Processing Inspection

A. We agree with the NAS study which encourages compliance-based processing inspection tailored to specific needs of the plant, products produced, location and other variables. Continuous online inspection by FSIS is not required to ensure food safety in meat and poultry plants that use hazard analysis/critical control point technologies which are monitored by qualified personnel. Variable time auditing and inspection is the recommended approach.

B. FSIS has recognized the willingness to change from traditional process inspection to voluntary compliance-based systems like TQC. Creation of a Processed Products Inspection Division, utilization of the FSIS training center to upgrade skills of

present personnel and positive results to date, strongly suggest that compliance-based process inspection is the preferred method.

C. We encourage the open door policy between FSIS and industry. Contrary to the NAS study which suggested this policy had detrimental results, we feel very strongly that this close communication network allows FSIS to be realistically involved with daily problems that translate into solid long range plans. The result of such open communication is a Federal agency that is far more effective in its mission than many other agencies.

D. We concur with the NAS study which recognized that state of the art temperature monitoring instrumentation be used to replace manual procedures where less than 100 percent inspection is provided. These technologies should be a vital part of process control systems that fit well within compliance-based inspection auditing systems.

Hazard Analysis Critical Control Point (HACCP) Approach to Food Safety

A. We agree with the NAS study that encourages FSIS to apply HACCP concepts to each and every step in plant operations and all types of enterprises involved in production, processing, storage and ultimate utilization of meat and poultry products. Hazards should clearly be defined as those associated with public health risk.

B. By focusing on hazards and control points related to public health concerns of biological and chemical agents over those which are aesthetic and not related to public health, FSIS could attain the highest degree of public health protection within available resources.

C. Continuous inspection is not needed to ensure food safety in meat and poultry processing plants in which HACCP have been identified and monitored by a qualified staff.

D. The identification of critical control points is the very foundation for construction of any modern quality control system. It has been used by FSIS to establish quality control inspection plans. One problem with traditional inspection is that an inordinate amount of time and effort is often spent on relatively minor deficiencies which have no relation to public health risk or economic adulteration. By broadening this concept to rank control points as critical, and for what specific reason, both FSIS and the industry could direct available resources to the most important problems areas.

New Technologies for Meat and Poultry Inspection

A. We concur with the NAS study to encourage the use of economical and efficient automated laboratory methodologies at all USDA and contract laboratories. Active participation in duplicate analyses and check sample programs is also encouraged. Computer-linked feedback of analyses to inspection and plant personnel who are operating under a compliance-based system, would lead to improved communication and corrective actions.

B. We encourage FSIS to develop a well defined research mission. Rapid and economical diagnostic methods for detection of potential public health hazards is the very foundation for compliance-based inspection which lends itself to animal certification and trace-back to the source.

C. USDA and FSIS scientists should be moved away from the desk and paperwork toward more active participation in professional meetings and industry seminars. Industry should be encouraged to better utilize FSIS and USDA scientific expertise.

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